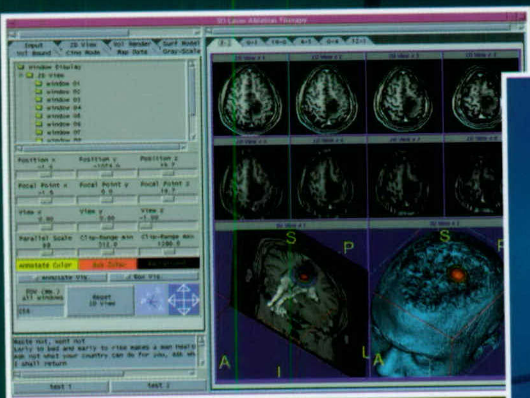
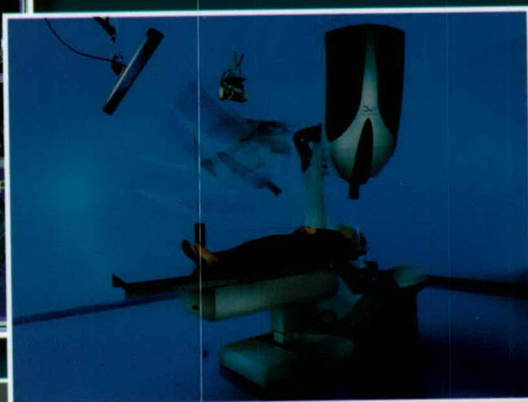
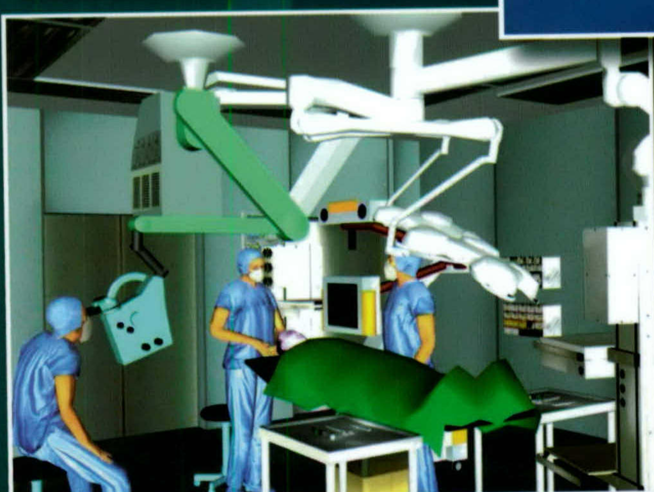
OR 2020

The Operating Room of the Future







- Operational Efficiency and Workflow
- Systems Integration and Technical Standards
- Telecollaboration
- Surgical Robotics
- Intraoperative Diagnosis and Imaging
- Surgical Informatics

WORKSHOP REPORT

18-20 March 2004

ISIS CENTER
Department of Radiology

Georgetown University Medical Center

AD__________________

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OR2020
THE OPERATING ROOM OF THE FUTURE

WORKSHOP REPORT
18-20 March 2004
Turf Valley Conference Center
Ellicott City, Maryland

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Top left: 3D laser ablation therapy. Courtesy of Ferenc Jolesz, MD, Brigham and Women's Hospital. Full image appears on page 52.

Middle right: CyberKnife® stereotactic radiosurgery system. Courtesy of Accuray, Inc. Full image appears on page 45.

Bottom left: Simulation of surgical workflow in the modern operating room. Courtesy of Heinz Lemke, PhD, Technical University of Berlin. Full image appears on page 20.

FOREWORD

This report presents the results of a Workshop titled "OR2020: The Operating Room of the Future," held March 18-20, 2004, in Ellicott City, Maryland. The objective of the workshop was to identify the clinical and technical requirements for integrating advanced computer-assisted and robotic technologies into next generation operating rooms and interventional suites. This was done through a collaborative effort involving physicians, engineers, and scientists.

First of all, I would like to thank the government agencies which provided the bulk of the workshop support: the National Science Foundation, the Army Medical and Materiel Research Command, and the National Institute of Biomedical Imaging and Bioengineering of the National Institutes of Health. Without their support, the Workshop would not have been possible.

I would also like to thank the corporate sponsors listed on page i and the back cover who enabled us to fund many of the special activities associated with the workshop, including the opening reception. Industrial participation is critical to the Operating Room of the Future, and it was gratifying to see so many industrial participants at the workshop.

All of the organizing committee members deserve thanks, but I would especially like to thank the members of the Innovative Surgery Committee at Walter Reed Army Medical Center for their efforts. In particular, Phil Corcoran, William DeVries, Eric Hanly, Ernest Lockrow, Michael Marohn, and Noah Schenkman were instrumental in shaping the workshop and selecting the participants. At Georgetown University, both Seong K. Mun and Michael Pentecost were tireless advocates for the meeting and provided resources and support.

At the Workshop itself, the student volunteers from Georgetown and Johns Hopkins were essential in keeping things running. Special thanks are due to Minh Vo, who was in charge of all of the logistics. My deepest gratitude is reserved for Audrey Kinsella, who drafted the final report and worked hard to ensure a quality product.

Finally, I would like to thank all the participants, who enthusiastically participated in the workshop and contributed to the energetic discussion in the Working Groups. I hope that this report is an accurate reflection of their views and opinions – we had an extremely talented and outspoken group and it was not easy to synthesize all of this material. But if we can bring the concepts discussed here to fruition, it should lead to improved health care and the patient will be the ultimate beneficiary.

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December 2004
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EXECUTIVE SUMMARY

The modern operating room requires an increasing number of new surgical instruments, monitoring and imaging devices, information systems, and communication networks. While these individual technologies are improving, attention must also be paid to integrating all of these resources so as to improve the quality and efficiency of surgical procedures. The OR2020 Workshop was organized by the ISIS Center at Georgetown University to identify the clinical and technical requirements for integrating advanced computer-assisted and robotic technologies into the next generation operating rooms and interventional suites. The Workshop built on previous symposia, including the Operating Room of the Future (ORF) workshop sponsored by TATRC in 2002.

Approximately 100 participants, including physicians, engineers, and scientists, met for two days in March 2004. The Workshop consisted of plenary sessions, a keynote speaker, and two breakout sessions which were divided by Working Groups. The six Working Groups represented key areas of research and development:

1. Operational Efficiency and Workflow
2. Systems Integration and Technical Standards
3. Telecollaboration
4. Surgical Robotics
5. Intraoperative Diagnosis and Imaging
6. Surgical Informatics

From the Working Groups, five broad areas of technology requirements were identified:

1. **Standards** for devices and their use in the operating room (OR) are sorely needed. Every aspect of OR activity today is affected by their absence. This was a concern repeated often throughout the workshop. The OR team of the future must also be interdisciplinary, a theme noted by other related initiatives, including the NIH Roadmap and its Research Teams of the Future theme.

2. **Interoperability of devices** is essential for improved care and throughput. Currently, most devices and computer systems function as stand-alone islands of information. A "plug and play" medical network is needed.

3. **Surgical robotics** continues to develop and will play a role in the Operating Room of the Future. Improvements in surgical robotics that build on their unique capabilities are needed.

4. **Surgery-specific image acquisition, processing, and display** are needed. The two-dimensional (2D) static images typically used today are not sufficient. Image processing and visualization tools must be made available to the operating room.

5. **Communications issues** must be addressed and aim toward attaining a common language, training requirements, and protocols. This goal also depends upon development of network standards to enable telecollaboration.

The report consists of eight chapters, beginning with an overview in Chapter 1. The Working Group reports are given in Chapters 2-7. The appendices in Chapter 8 include the workshop program, the list of participants, and a bibliography.

CHAPTER 1:
WORKSHOP OVERVIEW

1.1 INTRODUCTION

The "OR 2020 Workshop: Operating Room of the Future" was held on March 18-20, 2004, at Turf Valley Conference Center in Ellicott City near Baltimore, Maryland. The general objective of the workshop was to identify the clinical and technical requirements for deploying advanced computer-assisted and robotic technologies and biomedical modeling in next generation operating rooms and interventional suites. Integrated systems and the general character of the Operating Room of the Future (ORF) were defined, with the year 2020 used as a target timeframe. The workshop consisted of a series of plenary sessions and breakout meetings of the six Working Groups. Approximately 75 invited experts, both PhDs and MDs, participated. (See Figure 1 on the next page for a group photograph.)

The OR 2020 workshop was organized by the Imaging Science and Information Systems (ISIS) Center, Department of Radiology, of the Georgetown University Medical Center, Washington, DC; the Innovative Surgery Committee at the Walter Reed Army Medical Center, Washington, DC; and the Telemedicine and Advanced Technology Research Center (TATRC) at Fort Detrick, Maryland. The workshop was supported by the U.S. Army Medical Research and Materiel Command, the National Science Foundation, and the National Institute of Biomedical Imaging and Bioengineering at the National Institutes of Health. Corporate sponsors were GE Medical Systems, Karl Storz Endoscopy, MedStar Health/ Georgetown University Hospital, Olympus Surgical Division, Siemens Corporate Research, and Stryker Endoscopy.

This chapter begins by summarizing the common themes and recommendations from the workshop. Next, the focuses of the six Working Groups are presented in brief, followed by a snapshot of the workshop's rationale, planning process, and execution. Summaries of participants' views on needs and expected changes in the ORF are then presented, based on responses to a pre-workshop questionnaire that was sent to all participants.

This report can also be found on the World Wide Web, by starting at

http://www.caimr.georgetown.edu

and following the links to the workshops and the OR2020 workshop.

At the time this report was printed, we were also maintaining the conference web site at

http://www.or2020.org/

and additional workshop materials such as some of the presentations can be found there.

Figure 1: Photograph of participants

1.2 Common Themes and Recommendations

There were a number of common themes that were identified during the workshop and they are noted below. More details on the themes and specific recommendations related to them are presented in the Working Groups' reports (Chapters 2-7).

The five common themes that were identified are as follows:

1. **Standards** for devices and their use in the operating room (OR) are sorely needed. Every aspect of OR activity today is affected by their absence, from nonstandardized and incomplete patient records, to varied and unstandardized imaging formats of visual information that is needed during surgeries, to varied and sometimes imprecise language used in communicating among surgical team members.

2. **Interoperability of devices** is needed for development of a smoothly operating OR as well as for improved surgeries. Currently, most devices and computer systems function as stand-alone islands of information and their use requires a great deal of surgeons' time and effort.

3. **Surgical robotics** continues to develop and its role in the Operating Room of the Future is still being defined. Improvements in surgical robotics are needed to build on their unique capabilities such as precision, accuracy, ability to withstand ionizing radiation, and dexterity in small spaces inside of the human body.

4. **Improved, surgery-specific image processing and display** are needed for effective use in the OR. The two-dimensional (2D) static images that are typically available in today's OR do not accommodate the 3D and real-time imaging needs of surgeons in most specialty disciplines.

5. **Communications issues** must be addressed and aim toward attaining a common language, training requirements, and protocols for effectively performing advanced surgeries and using telecommunications-ready tools as needed.

The following recommendations were made, based on these five themes:

1. Standards, standards, standards. If there was an overarching theme of the workshop, this was it. Standards are needed in all areas, and must be developed through a concerted effort involving companies, government agencies, academic institutions, and perhaps standards organizations. Research studies of surgical workflow and efficiencies are required to develop practice standardization and thus realize improvements.

2. Progress on the first recommendation will also enable progress on device interoperability. It is recommended that research be devoted to developing common user interfaces among medical devices, and that the device industry take the lead in performing this research with input for academic institutions and government agencies. A "plug and play" architecture for medical devices is also needed.

3. Research in surgical robotics should focus both on improving the capabilities of these systems and integrating them with the surgical workflow. These systems could ultimately help improve patient safety by incorporating built-in safety checks and integrating them both with imaging and the electronic patient record.

4. Attaining advanced and improved surgery-specific image processing and display systems requires engineers and designers to work with surgeons to identify the needs and risks in using these systems. Readily available and flexible, real-time 3D imaging systems that use one standard platform for all imaging modalities are needed in current and future ORs. It is recommended that manufacturers and the device industry as a whole be encouraged to build imaging products that enable surgery-specific work.

5. A well-developed, dedicated medical network is needed to enable routine telecollaboration. An industry-grounded meeting to be attended by government stakeholders (including lawmakers), industry developers, telecommunications industry personnel, and surgical personnel should be arranged to address the needs of telecollaboration in medicine and surgery.

1.3 WORKING GROUPS

The OR2020 workshop consisted of plenary sessions and Working Group meetings during an intensive two-day period. The Working Groups each were charged with investigating a specific clinical and technical area related to the ORF. The six Working Groups were as follows. Group 1: Operational Efficiency and Workflow; Group 2: Systems Integration and Technical Standards; Group 3: Telecollaboration; Group 4: Surgical Robotics; Group 5: Intraoperative Diagnosis and Imaging; Group 6: Surgical Informatics. A brief summary of each group's work is as follows:

Working Group 1: **Operational Efficiency and Workflow.** This group focused on examining requirements for achieving increased efficiencies in the OR. These requirements focused on needed mechanisms for accessing and obtaining correct and current patient-related information and scheduling, and accessing use of correct surgical tools. The group also discussed developing surgical practice standards that define day-to-day, step-by-step surgical workflows.

Working Group 2: **Systems Integration and Technical Standards.** This group focused on the need for interoperability among a broad range of devices that are used in the OR. To achieve seamless integration among devices, a standard interface for interoperability among these technologies could be developed using a plug and play platform. This group also discussed the need for device standards that will enable configurability and easy use of these tools in the OR.

Working Group 3: **Telecollaboration.** This group focused on current and future uses of telecollaboration for purposes of remote consultation, mentoring, monitoring, robot manipulation, and other functions. An absence of standards in every facet of this form of telecommunications-assisted delivery was noted by this group. Standards are needed in areas related to clinical uses of telecollaboration (such as training). Other needed standards are related to technical requirements of telecollaboration (e.g., for a low latency data compression algorithm that will enable low bandwidth synchronized transmission of data to the OR). Finally, this group identified significant regulatory and legal hurdles that are slowing adoption of telecollaboration in the OR.

Working Group 4: **Surgical Robotics.** This group discussed the many clinical benefits of using robotic systems, particularly those that complement and extend human capabilities in the OR. Meeting technical needs for improving surgical robotics use requires building on robots' unique capabilities, such as their advanced precision, accuracy, strength, and dexterity. This group also discussed the importance of risk and safety issues pertaining to the use of robots in the OR.

Working Group 5: Intraoperative Imaging. This group focused on a central issue in intraoperative imaging today: namely, the difficulty for surgeons to obtain information from imaging devices in the OR. The need to present images in interactive and 3D imaging modalities, and for developing the capabilities to integrate and manipulate these data, were discussed.

Working Group 6: **Surgical Informatics.** This group focused on defining the nascent discipline of surgical informatics and identifying certain limitations that are impeding its development. The group noted a particular need for informatics systems that integrate preoperative, operative, and postoperative information and make it available where and when needed. In addition, a set of unified standards for procedures and use of surgical informatics must be defined and implemented, this Working Group concluded.

1.4 Workshop Rationale, Planning Process, and Execution

1.4.1 Rationale

A number of meetings that focused on needs in the ORF have been held in recent years. The OR2020 Workshop was committed to addressing issues that have consistently arisen at these meetings and elsewhere in discussion about the ORF. These issues include the need for widely adopted standards, concerns about ensuring patient safety, and the uncoordinated use of technology in the OR. Identifying mechanisms to address these issues and posing recommended solutions was the rationale for holding this workshop and inviting both clinical and technical experts to participate and share their views.

1.4.2 Planning Process

Planning for the OR2020 Workshop began in the Fall of 2002, when the ISIS Center at Georgetown University Medical Center began to formulate a broader direction for studying the ORF and its needs and purposes. It was felt that organizing a workshop was a good way to obtain a better understanding of this field of growing interest and concern. Collaboration with the Walter Reed Innovative Surgery Committee and TATRC was initiated. Funding was solicited from various agencies, and preparations were begun in earnest in the Summer of 2003. The organizing committee met several times during the Fall of 2003 to create the final program and identify participants. Invitations were sent in late 2003, followed by a pre-Workshop questionnaire. The Workshop was held March 18-20, 2004.

1.4.3 Execution

The Workshop consisted of plenary sessions and Working Group meetings. The plenary sessions were aimed at providing background for both clinical and technical areas. The Working Groups focused on specific areas of concern in the ORF, such as intra-operability of devices, telecollaboration needs, and surgical robotics. Each Working Group had a technical leader (PhD) and a clinical leader (MD). The Working Group leaders and participants are listed on the first page of each of the individual Working Group reports (Chapters 2-7).

The Workshop program is presented as Appendix A on page 64. The OR2020 workshop began with a reception on the evening of Thursday, March 18, followed by an organizing committee and Working Group leaders' meeting. The opening session was held the next morning and included clinical and technical overviews on the evolution of surgery, a view of a testbed ORF at the Massachusetts General Hospital, and a panel discussion of surgical specialties and practitioners' needs in the ORF. These clinical plenary sessions were followed by technical presentations on topics such as device independence in the OR, the state-of-the-art in robotics, image-guided therapy, and surgery-specific workflow. Additional plenary sessions followed after a break, and included topics such as interventional oncology and the future of imaging. Meetings of the six Working Groups were interspersed throughout the workshop days, with time also allocated for summary presentations following most of the Working Group meetings.

There were two extended breakout sessions for Working Group meetings. Each Working Group was assigned a specific task, as follows:

Breakout Session 1: Current status and clinical requirements
Task 1: Review contemporary issues in each Working Group's area in today's OR.
Task 2: Define the clinical needs for contemporary and future ORs.

Breakout Session 2: Technical requirements and research priority formulation
Task 1: Based on clinical needs, define the technical requirements.
Task 2: Summary. Prepare a list of research priorities and recommendations.

Working Group status reports were presented twice during the Workshop, in 10-minute sessions to the entire conference audience following the first and second Breakout Sessions.

To move forward quickly during the Workshop, a great deal of preparation was done prior to the Workshop. In particular, a pre-Workshop questionnaire was sent to all of the participants which asked them to identify research issues and suggest relevant references. The questionnaire served to get all of the participants thinking about the field and provided excellent background for the Workshop process. General questions included:

1. What are the main technical problems and research needs for the ORF?
2. What are the major infrastructure and administrative issues that must be addressed to develop the integrated ORF?

As part of the questionnaire, participants were asked to recommend three papers that were relevant to the field and a bibliography was generated which is presented in Appendix C. Most of the participants responded and the responses were used to help generate a 31-page pre-Workshop report. This report provided general background for each Working Group, summarized the questionnaire responses, and included a bibliography. All of this effort served to acclimatize the participants beforehand so that informed discussion could move ahead quickly at the Workshop. The questionnaire itself and all of the responses are available on the Workshop's web site, as noted at the end of section 1.1.

1.5 PRE-WORKSHOP QUESTIONNAIRE

As noted, a pre-Workshop questionnaire was sent to all attendees, and in addition to several general questions, the questionnaire contained three specific questions for each Working Group:

1. What are the major technical problems relevant to your Working Group?
2. What other factors are relevant for your Working Group?
3. What procedures could benefit most from advances in this area?

The responses to the specific questions from the Working Groups are briefly summarized here. Participants were encouraged to look at all the responses, and these were made available prior to the workshop.

1.5.1 Working Group 1. Operational Efficiency and Workflow

Summary of responses

1.5.1.1 Major Technical Problems. From the questionnaire responses, participants agreed that information flow is a critical concept. One participant suggested that there is a lack of information technology for the OR; and another participant described this as a lack of situational awareness. Another participant suggested that automation (such as use of radio frequency identification devices, or RFID) could reduce time and errors while improving efficiency. Finally, it was suggested that there is a lack of real-time information regarding upstream and downstream processes, which makes the system slow to respond to variances that occur in the OR (and there can be a lot of variances).

1.5.1.2 Other Factors. Several other factors were identified as important for operational efficiency and workflow. The need for more training of staff was emphasized. The culture of the OR and its slow acceptance of new technology were listed as barriers. The myriad of paper records is a problem. Management of unplanned events (which is a regular occurrence) is difficult. In addition, one respondent noted that small increments of saved time that do not result in improved throughput (more cases or reduced overtime) are of limited utility.

1.5.1.3 Procedures. In attempting to identify procedures that could benefit most from improvements in operational efficiency and workflow, most respondents noted that all procedures could benefit. One respondent noted that these improvements were particularly suited to surgeons who do 60-to-80-minute procedures that have limited variability. Another respondent noted that an additional benefit could be improved patient safety.

1.5.2 Working Group 2. Systems Integration and Technical Standards

Summary of responses

1.5.2.1 Major Technical Problems. The major technical problem related to systems integration and technical standards is the lack of an accepted standard for device integration. The development of such a standard is no doubt a large undertaking, and one respondent suggested that what is needed is a clear understanding of surgical workflow and modeling tools. Another respondent noted that it is difficult to provide open systems while ensuring safety, security, and patient confidentiality. One more respondent stated that integrated control and communication systems require that manufacturers must be motivated by economic drivers, and must feel secure from experiencing legal and FDA repercussions. Finally, one respondent stated that there are no major technical problems and that the manufacturing sector has automated factory workflow for years with proprietary and nonproprietary systems.

1.5.2.2 Other Factors. There were a number of other factors listed by the questionnaire respondents. The proprietary interests of manufacturers were listed several times. One respondent stated that the manufacturers fear providing opportunities for competition. Another respondent noted that no large institution is pushing for standardization and that the regulatory environment discourages integration since the FDA clears devices only for specific "indications for use." Finally, one respondent stated that there is a lack of understanding (either too simplistic or overly complicated) of how systems integrate and of the issues that impinge on integration.

1.5.2.3 Procedures. In regard to defining procedures that can benefit most from advances in systems integration and technical standards, one respondent suggested that all OR procedures would benefit. Other respondents noted that minimally invasive procedures and image-guided procedures could benefit.

1.5.3 Working Group 3. Telecollaboration

Summary of responses

1.5.3.1 Major Technical Problems. While there were many responses to this question, most of the responses did not actually list technical problems. Instead, respondents identified related issues such as the cost of equipment and infrastructure and the lack of adequate support staff. It was noted that there was a lack of clinical trials that demonstrate the value of telecollaboration.

1.5.3.2 Other Factors. Several other factors were mentioned as limiting the use of telecollaboration. The major other factor listed was medical liability, including licensure and credentialing. In addition, there is no practical system for financial compensation of telementoring or for accommodation of time-zone differences. The lack of acceptance by third-party payers and state licensing agencies was also listed, as was the difficulty of scheduling collaborating physicians.

1.5.3.3 Procedures. A number of different procedures were listed that could benefit most from advances in telecollaboration. One respondent felt that every surgeon performing basic procedures in community practice could benefit from the mentoring delivered by an expert observer. Similarly, for advanced procedures, expert physicians would like the support of national and international experts. Another respondent suggested that among the best applications of telecollaboration would be demonstrating/observing the first few of any procedures that were unfamiliar to a physician. Still another respondent listed image-guided therapies and laparoscopic and robotic-aided surgeries as particularly appropriate for telecollaboration.

Also mentioned were time-sensitive procedures such as emergency trauma interventions and cardiac surgeries. One respondent listed as appropriate those procedures that are seldom performed by most practitioners – that is, those that are rare or those that are just becoming established routines. The same respondent also listed interventional procedures that require collaboration across disciplines such as cardio or vascular procedures.

1.5.4 Working Group 4. Surgical Robotics

Summary of responses

1.5.4.1 Major Technical Problems. Many technical problems were listed by the respondents. It was noted that current surgical robots are too big and too expensive. The lack of haptics was noted by one respondent. Another comment was that there are not too many operations that actually benefit from robotics and it can actually be a productivity disabler. One respondent suggested that the equipment's fault tolerance needs to be improved. Another stated that robots are difficult to use and generally require more set-up time, especially when registration and/or fixation is required. Finally, one person suggested that robotics are not being adapted to the surgeon's working requirements and the patient's bodily needs.

In terms of technical problems related to surgical instrumentation, one respondent noted that voice recognition is still not where it needs to be for real-world use. Another respondent listed the problems with minimally invasive surgery, including placement and navigation of the instruments. Respondents also listed the needs for both multimodality on-line instrument control and for an integrated view of all relevant navigation and physiological data.

1.5.4.2 Other Factors. Cost was the other major factor mentioned by respondents as limiting the use of robotics. Other issues included training, the large size of the instrument, and the lack of a demonstrated benefit for mainstream use of surgical robots.

1.5.4.3 Procedures. Several different procedures were mentioned that could benefit from advances in robotics. One respondent stated that any minimally invasive procedure that is currently expensive to do (in terms of equipment or OR time) and is very demanding could benefit. Another respondent felt that it would be most beneficial for procedures, such as neurosurgery and heart surgery, that have a "scaling barrier". Lengthy procedures or procedures that demand prolonged or exact motor control were also mentioned as possibly benefiting from advances in robotics as was any procedure requiring complex reconstruction. Bone-oriented procedures were also mentioned.

1.5.5 Working Group 5. Intraoperative Diagnosis and Imaging

Summary of responses

1.5.5.1 Major Technical Problems. A number of different technical problems were listed by the respondents. It was noted that high quality imaging devices such as CT and MRI are generally too large for the OR's physical environment. Radiation exposure is an issue for x-ray imaging, which is otherwise one of the more practical OR imaging modalities. Other respondents noted that devices designed for the OR have poor image quality, the information is still presented mostly 2D (no real-time 3D is available), and the information is anatomical only (i.e., it is non-functional).

Another respondent noted the lack of integration of molecular imaging methods into intraoperative diagnosis. There is a need for better molecular tracers, both in marker intensity and specificity. One respondent listed the issues as biochemical sensitivity, spatial resolution, knowing what tracers are appropriate for a particular clinical task, equipment size, and other special environmental needs.

More than one respondent stated that modeling is an issue. There is a lack of adequate models for virtual representations of internal organs. There is a need for real-time computation for deformable registration and reconstruction and updating of image models.

Finally, it was noted that there is a need for more reliable and less expensive tracking devices. There is a lack of adequate software tools to conduct reliable intraoperative analysis, and an absence of consolidation of all of the intraoperative information into a comprehensive format.

1.5.5.2 Other Factors. There were several other factors mentioned as limiting the use of intraoperative diagnosis and imaging. These factors relate to how to best integrate the equipment into the OR and the surgical workflow. Other key factors concern questions of cost, reimbursement, and equipment ownership. One respondent noted that the equipment was disruptive to the flow of surgery. It is cumbersome, inconvenient, and requires collaboration with other departments to insure the availability of a technologist in the OR without whom the surgeon cannot operate. Another respondent listed other factors including sterile field violation, applications not designed for surgical OR interactions, and applications placed in geographically undesirable locations in the OR.

1.5.5.3 Procedures. A wide array of procedures were mentioned that could benefit from advances in intraoperative diagnosis and imaging. One respondent stated that most procedures were amenable to these advances but, in particular, the resection and therapy of malignant tumors would benefit most because use of this technology would allow the surgeon to remove all malignant tissue and reduce the damage to the neighboring anatomy. Another respondent similarly commented that all operations involving potential for vascular compromise of tissues were candidates, such as resection of brain tumors and metastases, resection of breast cancer, and auxiliary node sampling.

Other procedures that would benefit from advances included: prostate brachytherapy and surgery; cardiac interventions, neurosurgery, liver surgery, lung surgery, cancer surgeries, and orthopedics. The biggest growth is believed to be in soft-tissue MIS procedures. In the specific case of x-ray CT, probably some of the more immediate applications to benefit from advances are spinal, skull-base, and sinus procedures.

1.5.6 **Working Group 6. Surgical Informatics**
Summary of responses

1.5.6.1 Major Technical Problems. From the questionnaire responses, the major technical problem seems to be that surgical informatics is still evolving as a discipline. High quality surgical informatics systems do not seem to be available yet and there is no ontology or standard for their development. It is difficult to integrate the different types of information needed in surgical decision making into a coherent presentation and there is a need for decision support methods to integrate this information. There are no reliable content-based search techniques available and high performance computing has not been advantageously used.

In the area of surgical atlases, major technical problems include building quality anatomical atlases for organs other than the brain (where some preliminary solutions exist) and building patient-specific biomedical and simulation models. One respondent also noted that the bioinformatics field has provided many useful tools for this type of work, but it should be expanded to fully include images, techniques, and situational searches. By "situational searches," the respondent is referring to something like an intelligent agent that could examine the ongoing surgical operation and provide suggestions.

1.5.6.2 Other Factors. Several others factors were mentioned by the respondents as limiting the use of surgical informatics. In particular, it was noted that there was a lack of validation studies to convince the leaders in surgery of the value of surgical informatics. It was also noted that adopting use of surgical informatics in the OR will require a total change of the intra-operative procedure, a different workflow, and most of all, additional cost in time of the surgery.

Other factors limiting the use of surgical informatics that were listed by respondents included the need for a research OR that is charged with investigating the problems to be solved and the need to find surgeons who are willing to be involved in the development of these systems. The problems of cost and nursing turnover were also mentioned, along with the lack of inter-institution data accessibility and related regulations.

1.5.6.3 Procedures. Several different types of procedures were mentioned that could benefit from advances in surgical informatics. In particular, procedures with difficult or unusual complications, complex procedures that could benefit from extensive pre-planning, and any procedure with a long patient history were mentioned. One respondent listed the categories of intraoperative pathology, telementoring, telesurgery, and virtual reality applications including training and mission rehearsal.

Additional procedures suggested were orthopedics applications in which mechanical models were important, and neurosurgical procedures for which atlases would be beneficial. Another respondent listed tumor resection in critical organs and lymph node biopsies and resections. Finally, other suggestions included 1) bone procedures; 2) trauma care; and 3) vascular interventions, neural interventions, and tumor ablations.

1.6 REPORT OVERVIEW

The next six chapters (chapters 2-7) comprise the Working Group reports. Each report includes a capsule summary "At a Glance" page, an overview, and reports on clinical needs, technical requirements, and research priorities. Appendices include the Workshop program, a list of participants, and a bibliography suggested by the participants.

CHAPTER TWO AT A GLANCE: OPERATIONAL EFFICIENCY AND WORKFLOW

Overview

Improvements in operational efficiency and workflow in today's operating room (OR) will significantly impact progress in the Operating Room of the Future (ORF). There is a particular need to adapt today's advanced technologies to meet specific surgical needs. Among these tasks is adapting technologies such as smart tracking for patient records, and radiofrequency identification devices (RFIDs) for locating information about patients and equipment. Doing so successfully is necessary to attain improved efficiency and workflow today and in the ORF.

Clinical Needs

Achieving efficiencies in today's OR requires identifying mechanisms for:

- accessing and obtaining correct and current patient-related information.
- scheduling and accessing use of correct and operable surgical tools.
- developing consistent OR practices and prescribed workflow routines per procedure/per specialty.

Technical Requirements

Research to address these clinical needs should focus on developing:

1. Smart cards or nodes that store patients' complete medical records.
2. Tracking mechanisms to address OR-wide fragmentation of information about surgical tools (their location, operability, and scheduled use).
3. A system for creating focused and well-trained work teams to ensure that consistently efficient surgeries are completed.
4. Technical standards for the OR that define day-to-day, step-by-step surgical workflows (per procedures and per variable cases).

Research Priorities

This Working Group identified these priorities as the development of:

- Means for accessing comprehensive and current medical records.
- Standardized tracking and locating of surgical instruments.
- Surgical practice standards in the OR that reach across all specialties.

The full report of this Working Group appears on pages 15-22.

CHAPTER 2:
OPERATIONAL EFFICIENCY AND WORKFLOW

…THE REPORT OF WORKING GROUP 1

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2.1 OVERVIEW: COMMON PROCEDURES IN TODAY'S OPERATING ROOM

Standardized and improved workflow processes are central to ensuring the efficient operation of all hospital operating rooms (ORs) today. These processes are of particular importance in response to the continuing workforce shortages that are being experienced throughout the healthcare industry. Optimization of efficiencies in typical workflow processes is of special concern for health care providers, managers, and administrators, given the extent of OR-related costs in this, the most cost intensive sector of today's hospital. And there is a longer view that needs attention: Improvements in operational efficiency and workflow of today's OR will impact progress that will be achieved in the Operating Room of the Future (ORF).

Key issues in improving operational efficiencies and workflow in the OR concern implementing better management of a multitude of preparatory information and tasks that are needed before and during actual surgeries. Ready access to patient-related information is a central problem today in OR facilities in every type of hospital (military, academic, and community). Without this access, the workflow is disrupted and surgeons are less productive. Therefore, the need to improve management of information pertaining to patients (their records and histories, their needs, their scheduling, and so on) is key to ensuring efficient OR workflow and patients' safety. Standardized information technology for scheduling inpatients' and outpatients' appointments, tests, and other procedures as well as for scheduling surgeries is critical for achieving improved efficiencies in the OR overall.

This Working Group identified key resources and technologies that could be adapted to improve efficiencies and workflow in the OR. They are "key" in that they address the specific requirements of surgeons and their needs for improved workflow in the OR. Adaptations of, for instance, bar coding systems, radio frequency identification devices (RFIDs), and other tracking technologies were identified specifically as key for addressing chronic delays related to missing information about patients and surgical tools. And finally, a focus on modeling standardized surgical workflow practices for the OR was identified as an essential base from which to develop operational efficiency and workflow practices for the ORF.

2.2 Clinical Needs: Issues in Access to Information and Standardized Practice

Probably the most pervasive problem in today's OR has less to do with surgical technical advances than with the need for mechanisms to access and obtain correct paperwork for patient-related information. Surgeons must divert much of their time and attention beyond the matter of performing surgery adeptly. They must instead deal with a myriad of manually generated paperwork per patient which is sometimes neither all complete nor up-to-date. The potential for inefficiencies and introducing patient safety issues is increased as a result.

This Working Group discussed the very pressing need for a standardized access system from which surgeons and other OR personnel could obtain patient information and histories, patient room scheduling details, and information about location of equipment and the personnel who are trained to use it. Most particularly, there is a need for immediate access to patient information in the OR.

Clinical Areas for Needed Improvements

This Working Group identified and discussed three clinical areas needing improvement:

1. Poor access to patient and surgical information.

- Absence of a standard, computerized medical record for patients that documents their histories and their needs. These records must be current and complete. All future improvements on which these records are based (e.g., smart scheduling) depend on using a comprehensive electronic record as a template.

- Disparate patient and medical information and imaging systems that do not "talk" to each other, thus making accessibility issues difficult. An example of a stand-alone anesthesia record keeping system that is separate from the larger hospital information system (HIS) was provided as typical of such disparate islands of information that exist within hospitals.

- Multiple and disparate systems for tracking related work processes. For example, there are multiple scheduling systems used for tracking surgical in- and outpatients and another system for reserving surgical instruments and ORs.

- For surgery, in particular, an absence of a surgery-oriented standard for obtaining and viewing multidimensional data about patients during surgery. Improved paper-based records are not the only issue: there is also a critical need for real-time information regarding upstream and downstream processes in the OR. Without this information, the system is slow to respond to variances (and there can be very many variances, this Working Group was quick to note).

All of these access issues affect today's clinical practice and are detrimental to making optimal use of surgeons' time and expertise.

2. <u>Lack of consistent OR working practices or prescribed workflow routines</u>.

- An absence of standardized devices/systems in the OR. Multiple computer operating systems (e.g., Windows-based and DOS systems) are routinely used in the same OR but information cannot be shared between them.

- Inflexible devices/systems that are currently in place.

- Slow processes of switching between applications (and so, switching is avoided).

- Inadequate presentation of data (text, 1D, 2D, 3D, 4D) during the intraoperative and perioperative phases of surgery.

- Unavailability of a user-configurable information environment. In addition, especially during surgery, there is a need for accessing consistent visual images, preferably with a touchscreen, regardless of the display system that is used.

All told, today's surgeons who are using new technologies and imaging options appear to be adapting their immediate needs to what has been made available to them by manufacturers. They are devising "work arounds" rather than using advanced technology to improve on their surgical work.

3. <u>OR staff teamwork issues and communication deficiencies</u>.
Fragmented communications and varying levels of competency among OR team members are significant issues affecting efficiencies and improved workflow. These problems impact all aspects of surgery, including ensuring that:

- patients are appropriately prepared for surgery.
- patients' complete and up-to-date records are readily on hand.
- the correct tools are available and in the OR.
- a postoperative recovery area has been reserved.
- appropriate staff have been scheduled.

Informed teamwork is key to improving operational efficiency and workflow. The islands of communications that are typical of today's OR process simply do not work.

2.3 TECHNICAL REQUIREMENTS: SYSTEMS FOR IMPROVING WORKFLOW

Today, fragmentation of patient information and other needed records impedes optimal operation of the OR. One of the most "wished for" technical advances expressed by this Working Group was a "patient-centric" medical record that would be available to all healthcare providers and so better direct each patient's care.

Four of the most critical technical needs for improving OR efficiencies and workflow are as follows: 1) creating accessible medical records; 2) developing readable equipment locator/tracking mechanisms; 3) resolving OR teamwork/personnel issues; and 4) developing and following technical standards in the OR. The Working Group addressed these four issues separately as detailed below:

1) Creating accessible medical records

This group suggested that a standardized system for identifying each patient is critical for improving OR efficiencies. These suggestions included:

1. Creation of a smart card or smart node to be placed on every patient. This mechanism would store a patient's medical record and could be accessed easily by providers.

2. Means for assigning a unique identifier to all patients for improving access to their records. Coupled with this suggestion was the requirement for a robust electronic architecture for obtaining this information. The Internet was the suggested means for access, rather than using/depending on a certain computer or operating system that an individual is used to. Security and privacy concerns then became important.

2) Developing readable equipment locator/tracking mechanisms

Information flow is critical to the optimal and efficient use of the OR. However, this flow pertains to information transfer beyond the detail that is included in patient records. Fragmentation of information about patients, tools (location and scheduling of their use), and other critical components of the surgical process is pervasive in today's OR and must be addressed.

An integrated system for locating information and equipment is a key issue for improving OR efficiencies. This Working Group's suggested technical improvements for locating and tracking OR equipment included creation of OR-wide systems. Details about these systems are as follows.

1. Bar coding systems for identifying and tracking instruments and other equipment. These systems can help surgeons and other OR personnel locate equipment prior to the surgical procedure. This tracking can also help prevent the significant costs of unintentionally discarded or lost equipment post-surgery.

2. Standardized, automated tagging systems of all instruments and patients such as radiofrequency ID (RFID) of patients and equipment. Safety issues play a significant role here as well. There is a need for standardized scanning of patients after surgery and having each instrument tagged with an RFID mechanism to ensure that instruments have not been left inside patients.

3. Scheduling/tracking systems for specific equipment to have surgeons' preferred instruments in place.

3) Resolving OR teamwork/personnel issues

Varying levels of competency among OR team members affect efficiency and workflow in the OR. Designing teams that work well together and are well trained from among in-house staff is ideal, but many inconsistencies in scheduling and other issues have been shown to be a problem, this Working Group noted. In addition, cross-training usual OR staff is an inefficient use of resources.

One participant of this Working Group (who drew on his hospital's own experience) suggested hiring and dedicating a staff of procedure-specific technicians. This process worked particularly well for certain procedures, like laparoscopic surgeries, for which enormous amounts of set-up time and expertise are required on the part of surgical technicians. In this instance, the hospital also contracted with a commercial firm for acquiring all procedure-related instruments, and that firm took responsibility for ordering and maintaining instruments. Doing so ensured that the correct and operable tools and personnel were in place. Increases in efficiencies were realized by working with an informed, regularly scheduled team.

4) Developing and following technical standards in the OR

Standards for creating and integrating information about patients, equipment, and procedures are vitally needed at the outset in planning for an efficient ORF. To determine these standards, research is needed to define day-to-day, step-by-step surgical workflow practices and create surgery workflow models per procedures or per variable cases.

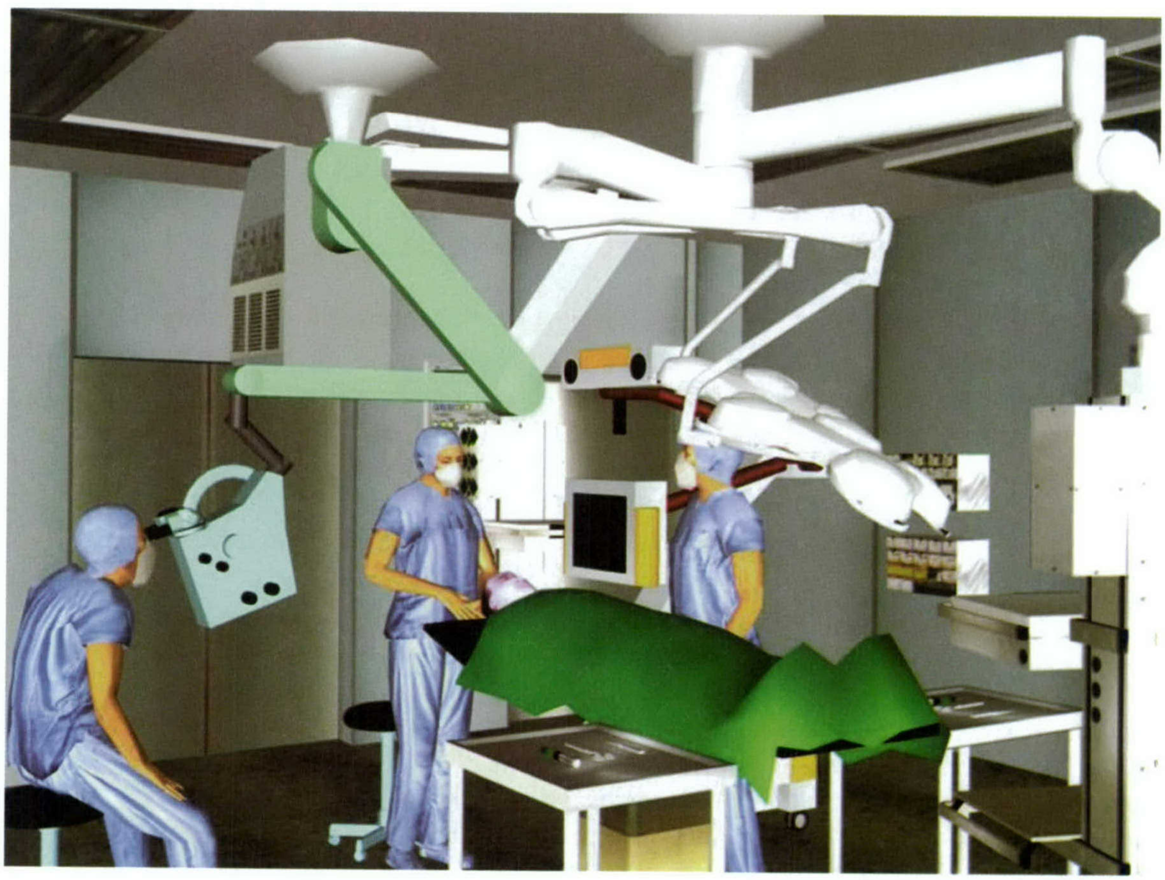

Figure 2: Simulation of surgical workflow
(courtesy of Heinz Lemke, PhD, Technical University of Berlin)

An example that might be used to better understand (and eventually improve on) OR workflows and efficiencies is the recent work by the Improving the Healthcare Enterprise (IHE) initiative and its definitions of workflows and efficiencies in healthcare outside of the surgical room. This body of experts develops recommendations for the healthcare industry on how to implement standards. (Note: IHE's members do not develop the standards themselves.)

Furthermore, the IHE initiative has developed "integration profiles" that enable consistent access to images and reports for certain medical specialties (such as radiology). Surgical profiles have not been developed yet, but they are needed, as this Working Group noted, as is a "surgical DICOM." Today's DICOM standard is not suitable for many imaging types that are needed in the OR (e.g., it does not cover real-time, 2D, and 3D issues, nor does it address interactivity).

2.4 RESEARCH PRIORITIES

The following research needs were identified as priorities by this Working Group.

- **Medical record access improvements**. A comprehensive, accessible, and standardized patient medical record must be developed. Ideally, the language and computer system that are used for these records should be universally accessible and should not be machine- or software program-dependent.

- **Equipment tracking improvements**. There is a need for equipment tracking mechanisms to address the critical issue of fragmentation of information about the tools that are needed for pre-surgical planning for the actual surgical procedures. New mechanisms must provide means to locate needed detail about the tools, such as information about specific instruments (brands, types, and so on) that are required during a surgery.

  Technical means for enabling this tracking should involve standardized use of:

  1. Radio frequency tracking of instruments and lap pads in the OR. Research should be focused on reducing the size of RFID tags and improving their performance in wet or other environments that are typically found in the surgical setting.

  2. A bar coding system for tagging and locating instruments throughout the hospital. System-wide mechanisms for this tracking must be developed so that the correct instruments are in the right place as needed.

- **Practice standardization/improvements**. Standardization of surgical practice across many spheres is needed to increase workflow efficiencies in the OR. These areas include standardization in:

  1. Developing technology across the system (for technology used by surgeons, by nurses, and other team members) and across specialties (for technology used in endoscopy, radiology, and so on). Surgical practice itself also needs to

be standardized and specific tools/brands decided upon in order for the surgical results to be consistent.

2. Scheduling of patients and comprehensive preoperative evaluation for their surgical procedures.

3. Preparing clinical teams who work together in the OR, with each member able to demonstrate skills in a particular technology's use. Increased education is obviously required to expand and refine team members' skill sets and enable them to plan ahead for next-day surgeries.

4. Defining and matching specific jobs/tasks and their roles in OR workflow processes. These roles need to be better defined to address the question: Who are the people that will be needed tomorrow in the OR?

5. Developing clinical guidelines per surgical specialty. Developing and following practice guidelines will achieve consistency in scheduling and undertaking routine pre-operative screening tasks, and otherwise better ready the patients for surgeries.

6. Acquiring surgery-oriented presentation of multidimensional data. Images ought to be consistent regardless of the display system that is used.

7. Developing standard operating procedures (SOPs) for the OR. A goal is to enable surgeries to operate like factories or assembly lines and produce a consistent, measurable product.

8. Studying individual work roles and activities to understand what people working in the OR do and say they do and why. Obtaining this information requires an ethnographic research study of the OR to be undertaken. From it, workflows can then be better defined from high to micro levels.

As a result of studying the overall workflow practices that characterize today's OR (including readying patients, preparing tools, performing procedures, and so on), a better understanding can be acquired of how these tasks can be performed efficiently in the future. These findings could lead to development of a needed, standard process model of surgical workflow. As a result, planners would have better information from which to assign and plan for human and non-human involvement in an OR that operates efficiently and productively.

CHAPTER THREE AT A GLANCE: SYSTEMS INTEGRATION AND TECHNICAL STANDARDS

Overview

There are wide ranges of medical devices used in today's operating rooms (ORs). However, many devices do not or cannot communicate among each other. A standard interface for interoperability among these technologies is therefore needed if simpler and seamless integration is to be achieved today and in the future. A platform comprising clinically connected devices that operate via plug and play standardization was the ultimate goal defined by this Working Group as desirable for the Operating Room of the Future (ORF).

Clinical Needs

This Working Group identified two critical steps for achieving systems integration and standards:

1. Defining information that is needed in the OR for clinical decision making.
2. Generating a systems platform for a multipurpose OR suite that facilitates reconfigurability for different surgical procedures and different surgeons' needs and tastes.

Technical Requirements

A plug and play platform must be developed. Such a platform is believed to be key for communications and control of multiple devices used in the OR. Standards that need to be included in this configuration were identified, including features pertaining to bandwidth, speed, and synchronization capabilities of the configured devices.

Research Priorities

This Working Group identified four priority areas for research. Among the most important:

- Developing "common" user interfaces among medical (especially imaging) devices. The device industry should take the lead on this research task.
- Devising and implementing a standard communications header for each device to identify itself, its task, ownership, and its capabilities.

The full report of this Working Group appears on pages 24-28.

CHAPTER 3:
SYSTEMS INTEGRATION AND TECHNICAL STANDARDS

...THE REPORT OF WORKING GROUP 2

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3.1 OVERVIEW: THE NEED FOR AN INTRAOPERATIVE AND INTEGRATED SYSTEMS PLATFORM

There are wide ranges of medical devices used in today's operating rooms (ORs). However, almost all of these devices operate independently or are incapable of communicating with other devices or technologies. Significant improvements in operating room efficiency and quality might be achieved by the design and implementation of an intraoperative and integrated systems platform.

A standard interface for interoperability is needed for all technologies used in the OR if simpler and seamless integration is to be achieved. However, the integration should be driven not by what components and technology matches are possible but by what makes sense clinically. In terms of integrating surgical equipment, what makes sense is taking a broader approach than just dealing with surgical information. The approach must integrate and incorporate the "physiological datastream"– that is, the anesthesia record, medical administration, and other information that is specific to the OR and patient activity.

This Working Group devoted significant time to identifying the building blocks that are needed to clinically and technically generate system platforms for multipurpose OR suites. A platform comprising clinically connected devices (operating via plug and play standardization) was the end goal desired for the Operating Room of the Future (ORF).

3.2 CLINICAL NEEDS: ISSUES IN DEVELOPING INTEGRATED OPERATING ROOM SYSTEMS AND TECHNICAL STANDARDS

At least two significant steps were identified as critical for building new, more useable systems for the OR. These are:

1. **Defining information that is mandatory in the OR.** Laying the groundwork for building an integrated and standardized system for the OR requires, first of all, determining what information is needed for clinical decision-making. Clinical requirements must be defined and articulated by surgeons and associated personnel and then conveyed to engineers and industry developers. This information will eventually need to be integrated into OR information systems and made readily available to OR clinicians.

These definitions of OR requirements must encompass not only the information and tools that are required in the OR but must also include and synthesize existing procedural protocols. There are currently varying types of protocols used in the OR. Clinical requirements (once identified) will define and generate the needed standards that represent a single, global protocol. Achieving this global protocol is the goal for attaining effective and measurable work in the OR.

2. **Generating a systems platform for a multipurpose OR suite.** A building block approach to defining clinical requirements and standards is needed from which to generate systems platforms for a multipurpose OR suite. Four key areas that must be addressed in standards development are as follows: imaging, visualization, control of devices, and communications. In addition, the platforms must facilitate reconfigurability that is needed for different procedures and for accommodating different surgeons' needs and tastes.

The building blocks of the OR informational system also have to continually define engineering requirements and so enable the system to meet platform standards for an application-specific, protocol-based workflow. There have to be multi-level device integration and high bandwidth data communications when required.

Too much technology?

An issue that arose during this Working Group's discussion was: Is there too much technology in today's OR to allow for clinical efficiencies? A need for surgical operation-specific procedural maps was voiced, as was the need for technology (and `modular technology, should needs change) that ought to be in the OR on a given day for achieving clinical efficiency. Ideally, each OR would be physically standardized to facilitate performing particular procedures and be physically mapped according to placement of tools and task-specific people.

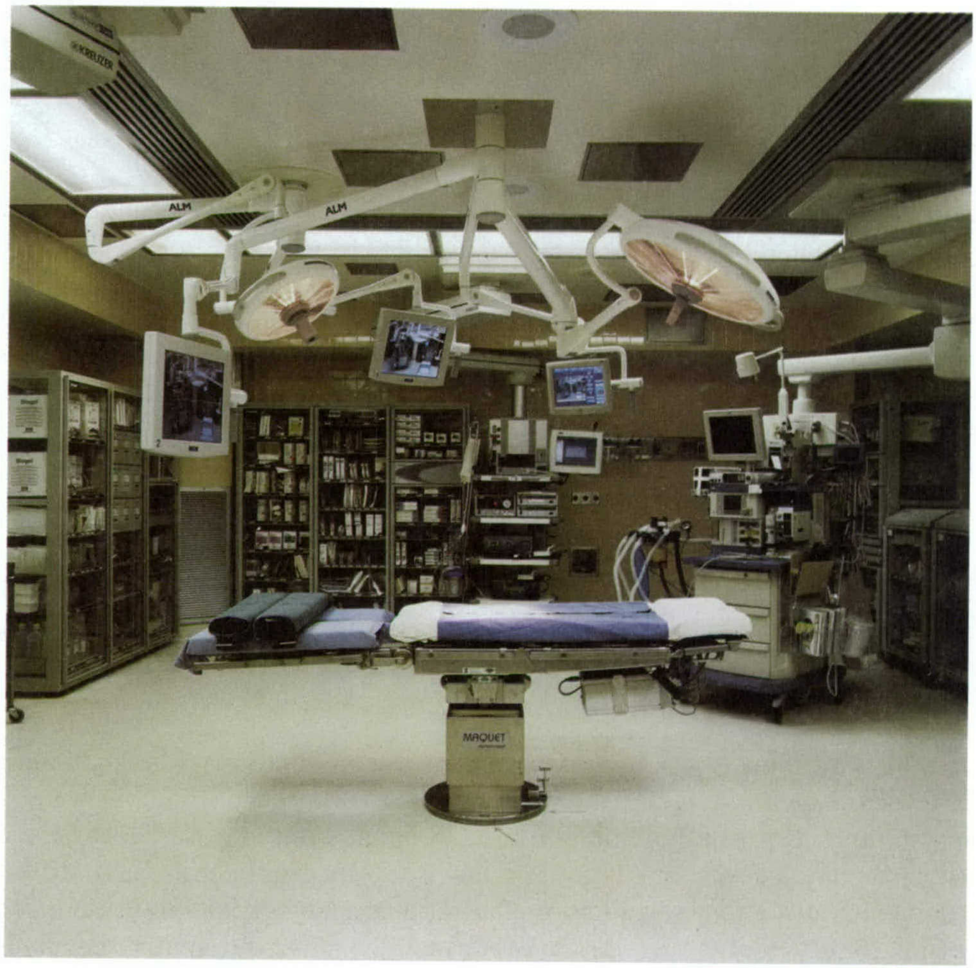

Figure 3: Operating Room of the Future at Massachusetts General Hospital
(courtesy of the Center for Integration of Medicine and Innovative Technology (CIMIT))

Planning for each procedure's requirements (and following specific, usual surgical routines) will indicate specific technology platforms that are needed for some procedures, not always for others. This standardized inventory is, as one group member noted, an extremely critical foundation from which to begin "before you start filling your room with standards of seven other different technologies." A goal may well be a requirement to design multipurpose, easily reconfigurable ORs. It was believed, however, that hospital administrators and hospital efficiency experts would not support separate ORs for each specialty. Standardization will occur only after the room is defined by the procedures (whichever operation is taking place).

Improved use of technology and current OR clinical requirements demand that planners:

1. Make sure that all machines and imaging modalities can talk to each other (and not interfere with other devices).

2. Move away from the non-interoperable multitude of devices that are used in today's ORs and which function in isolation.

3. Work toward creating neither single devices nor single systems but rather reconfigurable platforms that are based on standardized clinical requirements. These standardized features are key to improved use and clinical application-specific control of technology in today's OR. In particular, varieties of imaging modalities must be capable of being fused (registered) and displayed together.

4. Aim toward creating an image correlation protocol standard to be used as needed. However, a long-term goal ought to be achieving multi-level device integration that enables operator control and procedure-targeted systems configuration and will be most useable in the ORF.

3.3 Technical Requirements: Standards and Tools for Improved Operating Room Process Integration

The technology for creating standards or standardized interfaces among devices in today's OR needs to be identified. These systems must satisfy clinical requirements, and they must address what clinicians say they need in the OR.

At the outset, a plug and play system for developing this interface appears to be key for communication and control between multiple devices. Identifying requirements for this platform is essential. Specifically, devices that need to work together have to be identified as do their requirements for operation (e.g., in terms of bandwidth, speed, and synchronization).

Each device's range of capabilities has to be included in this configuration as well. Capabilities to transmit the status of its completed tasks to a designated location or via a built-in, real-time confirmation mechanism have to be included. Other features of the platform include authorization mechanisms for each device's use, and configurations that allow for only specified access to its capabilities by some designated users.

In addition, devices of the same type must be assigned to a specific class. The class must be understood as having specific capabilities and standards. For instance, insuffulators as a class have many capabilities, but some have all capabilities and others only have a few of these. Surgeons in the OR need to know about the particular capabilities of the insuffulator on hand so as to plan their work accordingly.

Although the need for building an improved platform is great and immediate, this Working Group agreed on the need for performing "historical due diligence" of device-related standards that have failed to date. Investigating these standards and why they did not succeed is a task that should be undertaken. The successes of certain other standards, such as HL7, USB, and DICOM, also need to be included in the ongoing research on workable system integration and standards for the ORF.

3.4 Research Priorities

At least four research areas were identified as priorities by this Working Group including:

- Developing "common" user interfaces among medical (especially imaging) devices. The device industry needs to shoulder this research task.
- Devising a standard communications header for each device to identify itself, and, specifically, its task, ownership, and capabilities.
- Developing a broad, encompassing plug-and-play system among devices for communication and control in the OR.
- Undertaking historical research of device-related standards, and studying which have been developed, which did not work or were not used, and why they failed.

CHAPTER FOUR AT A GLANCE: TELECOLLABORATION

Overview

Telecollaboration as practiced in the operating room (OR) uses telecommunications technology to connect surgeons and other medical professionals to another OR and its personnel. Telecollaboration can enable remote consultation, evaluation, mentoring/proctoring, monitoring, and performance of surgical procedures. It is a very new area of service delivery and its limitations as discussed by this Working Group are indicative of a developing field that lacks a terminology, established expertise, and accepted delivery protocols.

Clinical Needs

Defining terminology for telecollaboration was one identified need. Disseminating knowledge of telecollaboration's applications is also important for those who are new to this field, so that they can better plan interactions and determine telecollaboration's potential usefulness for particular cases. A lack of standardized practice, available equipment, and limited training were the main limitations identified as currently preventing greater use of telecollaboration. Advantages of using telecollaboration that were identified included accessing remote experts to mentor at a distance and reduce the learning curve time for young surgeons who are unfamiliar with particular procedures.

Technical Requirements

Technical problems in telecollaboration relate to adapting the technology specifically to surgeons' needs in the OR, and included the following:

1. Need for decreased latency in video data compression.
2. Lack of a standardized telecommunications network for the OR.
3. Lack of standardized data, resulting in too many variables among data that are delivered to surgeons in the OR.

Research Priorities

Research priorities must focus on developing technical standards for telecollaboration to promote interoperability. Challenges for the development of the field include involving industry and political-arena representatives for improving a nation-wide communications network and addressing licensure and privacy issues so as to enable wider adoption of telecollaboration and its effective use.

The full report of this Working Group appears on pages 30-38.

CHAPTER 4:
TELECOLLABORATION

...THE REPORT OF WORKING GROUP 3

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4.1 INTRODUCTION: A HISTORICAL VIEW OF COLLABORATION IN THE SURGICAL THEATER AND POTENTIAL USES FOR TELECOLLABORATION TODAY

Telecollaboration in surgery is an innovative approach to sharing experience and expertise and is enabled by today's advanced communications technology. The operating room (OR) of the nineteenth century was surprisingly collaborative, however. Surgeons, nurses, consultants, and other members of the healthcare team, as well as medical students, nurses-in-training, and other learners were, in many cases, free to come and go to the OR as patient care and learning needs required. With a name that is now a misnomer in the countries that still use it today, the operating "theater" was just that: a theater where people gathered around the process of surgery to contribute and learn. However, the advent of aseptic technique changed everything.

The OR of the twentieth century can best be described as "anti-collaborative." To even get to an OR today, individuals must change clothes – donning scrubs, booties, bonnets, and masks; enter physically isolated "suites" guarded by nurse managers whose principle objective (in the opinion of many would-be students at least) – is to block the entry of all but the most essential parties; timidly cross a brightly-colored line on the floor indicating the point of no return; and then finally enter further partitioned rooms. And all of this is just to get in the room! Should someone be so bold as to actually want to see the operative field, much less have physical contact with the patient, they must first cleanse themselves of integumental impurities and don yet another layer of sterile clothing. Thus the process of "collaborating" with someone in the OR has become, not surprisingly, very intimidating, resulting in a drastically reduced dialogue between surgeons and consultants, surgeons and nurses, surgeons and students, and surgeons themselves.

The OR of the twenty-first century can and must be different. Throughout the twentieth century, the introduction of local intercoms and telephones into hospitals began to reconnect the OR with the outside world. In the mid-1990s, the first telementoring in the OR using real time audio-video teleconferencing equipment furthered this connection, as did surgeons' use of telecommunication networks to remotely control a laparoscopic camera. On Sept 9, 2001, Jacques Marescaux ushered in the new millennium for OR telecollaboration when he controlled a Zeus telesurgical robot in Strasbourg, France from an office in New York City to perform the first transatlantic telerobotic laparoscopic cholecystectomy. The stage had thus been set for the advent of routine telecollaboration.

There is a range of current uses of telecollaboration, which in the OR, can enable surgeons and other medical professionals and robots to communicate with each other regardless of location. Telecommunication between experts or between experts and less experienced professionals, students, or robots has multiple functions. It can be used for remote consultation, evaluation, mentoring/proctoring, monitoring, and manipulation, and for actually performing surgical procedures.

Telecollaboration is particularly valuable in isolated areas where access to major centers and/or experts is difficult to achieve. It is particularly needed in rural settings as well as in remote areas such as on the battlefield, at sea, and in outer space. The field is still very new, however, and there are relatively few practitioners today. Nonetheless, technological advances in the past 25 years in video and computer communications have established the capabilities to enhance, compress, and transmit video signals and other information over long distances. More than ever, telecollaboration in today's OR is possible.

This Working Group identified some key issues for improving the delivery of telecollaborated services for the OR. Among these was the absence of both clinical and technical standards, a problem that poses significant limitations to the development of this nascent field. Among the other major drawbacks are limited tools for educating students and practitioners about this field and its effective applications, and limited communications technology that has been specifically adapted to surgeons' needs in the OR.

4.2 Clinical Needs: Defining a Frontier Field

At the outset of discussion, this Working Group identified a need to define terminology for surgery-related telecollaboration. This need is particularly important for telesurgeons obtaining licensing privileges and specifying what activities will be performed during a tele-intervention (and for which they will subsequently submit payment requests). Terminology is also needed for health care planners who are assessing options and examining the potential usefulness of tele-interventions for particular cases.

According to this Working Group, there is a great deal of misunderstanding about the meaning of "telecollaboration" in the OR. As a result, ill-defined and ambiguous terminology has surfaced. The following terms and definitions were discussed:

> **Teleconsultation**. Communication at a distance between two or more health professionals to "discuss" the diagnosis, prognosis, and treatment of a particular patient's case. This includes, but is not limited to, the use of email, telephone, and audio-video teleconferencing to exchange information between an operating surgeon and one or more other providers.
>
> **Tele-evaluation**. The appraisal, typically including some type of physical examination, of a patient distant from the health care professional. The most common media type used for this process is audio-video teleconferencing.
>
> **Telementoring/Teleproctoring**. The teaching and supervision of a less experienced surgeon by a remotely located expert surgeon. Telementoring includes giving real-time advice about the various mechanical steps of a particular operation. Audio-video teleconferencing is fundamental to this activity. Oftentimes, telementoring is enhanced with the use of telestration devices.
>
> **Telemonitoring**. The observation of another surgeon's or surgeon-in-training's performance during a surgical procedure. This practice can be thought of as "telegrading" that is typically done in real time, but can be accomplished via store-and-forward technology. Telemonitoring usually includes some assessment of the operating surgeon by the expert, but without the real-time expression of that assessment.
>
> **Telemanipulation**. The remote operation of a device (e.g., camera, needle, instrument, etc.) for a specific purpose (e.g., visualization, biopsy, etc.). This activity necessitates that control signals be sent across telecommunications lines in order to move the device. Telemanipulation is a limited subset of telesurgery (defined next).
>
> **Telesurgery/Telepresence surgery**. The performance of surgery (including all tasks typically assigned to a surgeon) at a distance using remote control of surgical robots over telecommunications networks. Telesurgery is bimanual remote manipulation of the tissue being operated upon with complete real-time visual access to the operative field. When using telesurgery to operate in conjunction with a local surgeon, telesurgery allows the remotely

located expert or consultant surgeon to "take over" as necessary to demonstrate the "next move," or to actually perform the surgery.

The sharing of expertise is key to all of these defined tele-activities. To date, surgical areas that have primarily been focused on telecollaborative efforts include neurosurgery, orthopedic surgery, and vascular surgery as well as telepathology. This terminology must be established to avoid confusion about the use of telecommunications-ready technology in the OR as well as to help people to better understand what the approaches are and how valuable they can be in teaching and mentoring.

An overwhelming goal of telemedicine has been to replicate on-site activity from a distance. Much of what is measured in telemedicine and judged successful focuses on how closely (and without incident) these replicated activities have taken place. For this reason, four other terms that also affect the use of telecollaboration were defined by this Working Group. These are:

Control Latency. The delay between when a remote surgeon moves a controller and when the surgical tool actually moves inside the patient. This time is a sum of the delays inherent to digitization of the controller movement, transmission of these digital signals to the patient's location, and electro-mechanical translation of these signals.

Visual Discrepancy. The delay between when something moves in the operative field and when the surgeon visually appreciates such movement at the remote location. This time is a sum of the delays inherent to digitalization and compression of the video signal(s) by the CODEC(s), transmission of the signal(s) across telecommunication networks, and decompression of the signal(s) by the remote CODEC(s).

Round-trip Delay. The sum of control latency and visual discrepancy – i.e., the time between when a remote surgeon moves a controller and when such translated movement is visually appreciated at the remote location.

Jitter. Real-time variations in the amount of delay introduced by variable traffic in telecommunication networks.

Limitations of the clinical uses of telecollaboration in the OR were identified by the Working Group, and included:

- uncertain and nonstandardized reimbursement mechanisms and amounts for telemonitoring (at least in the U.S.)
- high set-up costs of equipment and systems
- uncertainties about licensure, credentialing, and other legal-related issues (which can vary from state to state)
- extensive set-up tasks and time required for readying both the robotic components of the surgery and the telecommunications infrastructure, thus increasing the amount of needed OR time
- time consuming tasks for coordinating participants in teleconsultations (e.g., between teams or between just two surgeons, matching their capabilities, pinpointing schedule availability times, and so forth)
- uncertainties about telemedicine's use and HIPAA (health insurance portability and accountability act) compliance and privacy issues
- varying amounts of skills among mentors and collaborators (making it difficult to estimate amounts of time needed for teleconsultations)
- language issues and time zone coordination issues, especially affecting international consults
- limited knowledge about telecollaboration among user or potential users – what is available, how easy it is to use, and identification of appropriate applications
- variations in quality of video resolution at different institutions (depending on network capabilities) and as are needed for different procedures. For instance, for a 352 by 240 VHS quality video, approximately 1 Mbps per second (a relatively large amount of bandwidth) is required to send compressed images for telesurgery and telementoring. Lesser bandwidth may be acceptable for other teleinteractions.

Many of these issues are clearly related to an emerging and evolving technical field.

Particular advantages of using the technology were also identified (these, apart from telecollaboration providing access to specialty care and knowledge by remote providers). These advantages include:

- reduced need for on-site pathologists whose work can be done electronically on an as-needed basis (i.e., getting telepathology analyses immediately in the OR from surgical biopsies using a telerobotic microscope).
- shortening of the usual learning curve time for young surgeons and surgeons unfamiliar with particular procedures, as a result of telementoring/teleproctoring.
- real-time verbal, video, and imaging communications from which surgeons can assess the impact of what they are doing, rather than simply reviewing their work after the surgery has been completed.

Issues making telecollaboration less successful were identified as follows:

- Varying amounts of bandwidth availability at different institutions, and the potential for loss of signals that can affect quality of service (particularly in regard to unpredictable latency issues).

- Absence of network standards for reliability and security ensured during telecollaborative interventions.

- Lack of standardized communication skills between mentors and telesurgeons. Improving these skills is needed so that teleconsultations and other tele-interactions will be understood and successfully accomplished.

Figure 4: Laproscopic telesurgery case from
Center for Minimal Access Surgery, Hamilton, Ontario, Canada
(courtesy of Mehran Anvari,MD)

4.3 TECHNICAL REQUIREMENTS: STANDARDIZING SERVICES SPECIFICALLY FOR THE OPERATING ROOM

Limited standards in technical matters such as data compression and synchronized transmissions greatly affect the quality of telecollaboration services in today's OR. As this Working Group noted, the quality of service is dependent on packaging and aligning different data types: audio, video, and commands. Losing quality of one of these data types (say, losing audio for 5% of the time during a teleinteraction) may or may not be an issue; however, losing control of commands for as little as 5% of the time can result in serious problems.

Four key technical problems related to telecollaboration in the OR are as follows:

1. Data compression and latency issues. There is a need to develop a low latency data compression algorithm for low bandwidth synchronized transmission of data to the OR if disparate data types are used. To date, emphasis on a compression algorithm has focused on decreasing packet loss rather than on decreasing latency. However, although latency is less of a problem for certain aspects of telecollaboration, such as tele-evaluating or telemonitoring, it is a significant problem when telesurgery is practiced.

2. Telecommunications network development. There is an urgent need for good and reliable telecommunications networks. Networking issues are currently directed by commercial vendors and have varying capabilities. This Working Group suggested the need for development of a new (or improvements on existing) national/international telecommunications network that should be designed from the perspective of telesurgeons. This network should address some of the issues that are unique to telecollaboration in the medical community.

3. Absence of standardized data. The need for standardized data transmission was recognized by this Working Group. However, given the many disparate data streams that become available during telecollaboration activities, it is not yet clear which of these data need to be synchronized or standardized in one presentation format and be of a certain quality. Standardization of various data that are transmitted to the OR is a topic that requires future research.

4. Human factors interaction issues. It is still not well understood how humans respond to telecommunications and accept its use. Several early studies have noted that some OR personnel disliked being audiotaped, videotaped, or otherwise "watched," and sabotaged the tele-interactions (by covering up the cameras, for instance). More study is required to understand the extent of this problem and develop strategies for handling it.

4.4 RESEARCH PRIORITIES

Telecollaboration is still very much in frontier territory, and many research needs and priorities were suggested by this Working Group. This group's members agreed that routine telesurgery is still a distant goal, but that telementoring and teleconsulting are feasible at this early stage of telecollaboration's development.

For growth of the field, research ought to:

1. Identify practitioners of telecollaboration, and identify the kinds of cases and payers involved in their practices. Compiling this information may help to justify the case for making telecollaboration become a priority item for research.

2. Study and document telecollaboration's efficacy. A study of clinical efforts may note a reduction in morbidity, for instance.

3. Undertake cost analyses and demonstrate cost effectiveness of telecollaboration efforts.

4. Study intangible issues like patients' preferences for not having to have to travel for surgery.

5. Develop practice standards, especially for troubleshooting. For example, standard procedures to follow when systems inadvertently shut down or a complication occurs are needed. Standards will have to define a certain expectation of care in telecollaboration. The need for using back-up systems should be indicated. There should also be a standard plan for interventions by other personnel in the OR or at remote sites to try to correct problems that are encountered during the telecollaborated episodes of care.

Several members of this Working Group also noted the need for developing technical standards for OR data devices. The overarching priority is to establish routine telecollaboration in a well-developed, dedicated medical network. Critical to the operation of this network are the following needs:

- Develop better codecs to reduce latency in the OR. The lack of cost-effective devices for compressing/decompressing video signals at a rapid rate is limiting surgeons' telecollaborative ability.

- Develop a compression algorithm that is ideally suited to the needs of telecollaboration. This algorithm would place a greater emphasis on low latency rather than low packet loss, picture quality, and related components of telecommunications.

One challenge for developing this network is to convene an industry-grounded meeting to discuss the surgical needs of telecollaboration and telecollaborators. The telecommunications industry must be involved in this discussion.

A second challenge calls for managing a political agenda, one that addresses issues such as licensure, privacy, and consent. There is a need to send a clear message to political decision makers that this agenda must be addressed for work in telecollaboration to advance in the medical community.

CHAPTER FIVE AT A GLANCE:
SURGICAL ROBOTICS

Overview

Advanced robotic devices and systems which provide more accurate and minimally invasive surgeries continue to develop. A range of robots are available today for tasks such as hip replacement in orthopedics, camera positioning for laproscopic surgery, minimally invasive cardiac surgery, and needle placement for image-guided interventions. To take full advantage of robots, we must employ them to do things that humans cannot do, such as motion scaling and tremor reduction. Experts should also establish safety protocols for the use of surgical robotics.

Clinical Needs

The main clinical benefit of robotic systems is to improve on the capabilities of surgeons by avoiding problems such as fatigue and error. Robots have been developed for many clinical procedures but the use of robots is still in its infancy. Task-specific micro-robotic applications such as transnasal and transcellular robotic surgeries are among the possible new procedures that might be established.

Technical Requirements

Surgical robotics must build on their unique capabilities including precision, accuracy, strength, and dexterity especially in very small spaces inside of the human body. Technical advancements in robotic surgery must focus on both improved imaging control and process planning to make a better fit of robots in the OR. In addition, improving safety in the OR is one ultimate goal for advanced robotic systems.

Research Priorities

Means for mining the routinely large and complicated streams of surgical data that are generated during each procedure should be investigated by surgical robot system developers. These data can be used to better understand surgical work routines and to create robotic systems that can safely perform tasks that complement and exceed the capabilities of today's surgeons.

The full report of this Working Group appears on pages 40-48.

CHAPTER 5:
SURGICAL ROBOTICS

...THE REPORT OF WORKING GROUP 4

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5.1 OVERVIEW: ROBOTS AND THEIR NEEDED SURGICAL ROLES IN TODAY'S OPERATING ROOM

Advanced robotic devices and systems which provide more accurate and less risky surgeries continue to develop. Accepted benefits and advantages of robotic technology include: enhanced manual dexterity; computer scaling to "miniaturize" surgical movements; filtration of ultra-high and high-frequency signaling to reduce or eliminate surgical tremor; and binocular stereoscopic 3D visualization for more accurate surgical field visualization and overall processing of imaging data. Future capabilities which need to be exploited and developed include: integration and automation of all processes in the operating room (OR) environment, from patient flow considerations to workload projections; and incorporation of radiofrequency identification device (RFID) technology to stock and replenish logistical supplies and to track personnel movement in the operating room of the future (ORF). Potential uses of surgical robotics might be limited to performing surgical tasks or be extended to automating all aspects of the ORF.

<u>Current Uses and Capabilities of Surgical Robots</u>

A variety of surgical robotic devices is available today and has a range of functions in the OR environment. Some robots function as surgical assisters in orthopedics, and others can be used as a surgeon's "third hand" for moving the camera during minimally invasive procedures. Others exist to perform or facilitate telesurgery, telemonitoring, tele-mentoring, or true telepresence instruction. Still other robotic devices perform or assist with image-guided interventions.

Transforming existing robotic devices into all-purpose devices or systems was a concept that emerged from discussions of this Working Group. This change would be facilitated by integrating both the image and information processing capabilities, and the visualization and task performance systems onto a multi-purpose workbench-like platform. Robotic devices would be designed with automated tool changers, thereby enabling robotic devices to change tools rapidly and precisely in order to perform a multitude of tasks in the OR environment. This capability could easily alter a robotic device's function and make it a more universal or multi-purpose device. As a result, robots could be made more useful in the neurosurgical, orthopedic, cardio-thoracic, and urological suites.

In addition, the use of these robots need not be limited to surgical task performance. The OR environment is an exceedingly complex environment and requires robots to function with far more capabilities than merely operating as tools to perform simple tasks. Robotics could and should be used to facilitate the overall performance of complex surgical interventions in the technologically advanced environment of the ORF. These capabilities will involve information management, data processing, image processing, image-guided intervention, complex and minimally invasive task performance, and control of the OR assets, supplies, and personnel as well as management of the flow of patients within the process of surgical intervention.

Improving the capabilities of robotic systems must differentiate the machines' abilities to perform procedures which humans can do from those which humans cannot do. Robots and computer systems can process data and acquire data and images in manners far superior to humans. A challenge is to take the human ability to interact with the surgical environment and make decisions, then to translate these abilities into task performance needs for a surgical robotic system.

5.2 CLINICAL NEEDS: DESIGN ISSUES FOR TARGETING BEST USES FOR SURGICAL ROBOTS

This Working Group generated lists of the potential benefits and advantages as well as drawbacks of robotic systems. These lists facilitated discussion of design issues for targeting the best uses for surgical robot systems in the ORF. Among the positive features are the abilities of robots to:

- filter ultra-high and high-frequency signaling from a remote slave manipulator to a master controller and eliminate surgical tremor or tremulousness, which all human beings have to some degree.
- provide vastly enhanced 3D binocular stereoscopic visualization through the videoscope.
- provide computer scaling of motion so that surgeons can very accurately perform precise microsurgical movements. This capability enables complex microsurgical procedures such as sewing on small blood vessels or on the human heart to be performed.
- avoid fatigue and its effects.
- enable repeatability and reproducibility.
- reduce surgical error by integration with informatics systems.
- provide enhanced manual dexterity for surgical task completion as compared to using currently available minimally invasive instrumentation.
- be used safely inside of x-ray and MRI devices and in other unfavorable or hazardous environments.

However, there are drawbacks to the use of robots as they can be:

- cumbersome.
- costly. Both the lengthy set-up and operative times increase OR costs overall, as well as the initial cost of the equipment.
- limited in portability or mobility. Currently robot are mostly stationary and have to be located near or attached to the OR table to know where the effector arms are located in relation to vital anatomic structures. Once the robotic system is deployed inside of the body, it cannot be moved. More importantly, the patient cannot be moved in relation to the position of the robotic system's effector arms, or else the positional sense will be lost. This immobility constraint is highly limiting for surgeries that require a large amount of translational motion during the operative intervention, such a retroperitoneal lymph node dissection. In this example, the current systems cannot move easily from deep in the pelvis to the diaphragm.
- limited in tool sets and the capabilities of the tools. All tools have to be independently operated by hand or be attached to the end of the robotic system's effector arms. Technologies such as surgical clip and surgical stapling

applications, and energy sources such the harmonic scalpel and argon beam photocoagulation devices are currently not available for robotic surgery because they cannot be placed at the end of a robotic arm. The same situation exists for other energy sources such a cryotechnology, radiofrequency ablation, microwave, and laser technology.

Needed Improvements

1) Non-specialized robots. Robotic systems must address the varied clinical needs of surgeons and surgical sub-specialists. For instance, ENT surgeons need a specialized set of surgical instruments to accomplish a radical neck dissection as compared to neuro-surgeons, who need a completely different set of instruments to accomplish brain or nerve resections. ENTs or general surgeons need to do conventional cut-and-sew types of procedures while neurosurgeons need to use energy sources to perform ablative procedures. However, because today's robotic systems are procedure specific rather than being specialty or discipline specific, none of these clinical needs are being met.

Current systems are in fact severely limited in the flexibility or applicability to a broad range of specialties or surgical procedures. To address this problem, this Working Group suggested that if robotic systems were not as specialized, they would be employed by a broader range of operators.

2) Micro-robotic applications. Improvement in robotic systems in the areas of micro-robotics applications would extend the range of surgical possibilities. For instance, micro-robotic applications would enable transnasal, transclival, or transcellar approaches. Using robotic technology under an operating microscope would enable intracranial or base of skull surgeries, which are completely limited by the absence of microscopic instruments. Other applications of robotic microsurgery which should be developed are hemorrhage control and tumor resection.

3) Integrated imaging. Image overlay and imaging with interactive robots are potential areas of improvement in robotic system technology. As a result of using advanced imaging technology, the performance of certain operative interventions may well be conducted in different manners. For example, increased imaging may enable a neurosurgeon to expose an aneurysm at the base of the skull differently. The ability to visualize the brain in different presentations would dramatically alter the approaches to the brain tumor or targets of surgical intervention. Similarly, if a surgeon could visualize a tumor in the lung in 3D and reconstruct the holographic imagery in any way desirable, the tumor could be approached from any number of different angles and possibly increase safety.

4) Increased mobility. Robotic systems must have a higher degree of mobility or transportability than today's commercially available systems allow. Current systems are not particularly mobile within the human body and are not transportable between OR

environments. Without increased mobility, surgeons are constrained by using only port access approaches and a single pivot point from which all manipulations must occur. However, with increased mobility, a heart surgeon could, for example, maneuver through a blood vessel such as a vein, rather than have to operate through a conventional incision in the right atrium of the heart to fix a hole in the heart. Thus, increased mobility would provide better and more minimally invasive access to the human.

5) Creative design for practice use. Today's robotic system technology is limited by its being viewed simply as surgical task performance devices. Robots are understood as being tools that are attached to effector arms in a manner exactly analogous to a human being with arms attached to the body and run by direct neural attachments. However, broader and more creative concepts need to be explored. Among these is the concept of remote control of devices which could swim through the vascular tree or crawl through the gastrointestinal tract and accomplish diagnostic or therapeutic tasks. New systems might automate certain robotic tasks, and include a drivable visualization system to move the optics to another anatomical location.

Design and Planning Efforts

An optimal or "dream system" for surgical robotics in the future would have many applications in the ORF. This Working Group discussed design and planning efforts in terms of needed uses and tasks of robots, as well as educational needs.

1) Uses and tasks of robots in the ORF. Design of robotic systems for the ORF needs to focus on whether robots will be used in only some or all of the surgical process. Decisions have to be made about possibly limiting the uses of robots to the pre-operative planning stage or the post-operative assessment. The group suggested using surgical robotics as assistants that perform time consuming tasks. For example, a robotic system could prepare the hundreds of sutures needed during a protracted open heart surgical procedure. A more ambitious goal for surgical robotics would be to make the entire OR intervention completely robotic and automated in nature. As such, procedures in the ORF would be analogous to work on an assembly line in the automobile manufacturing industry. These systems would extend the use of surgical robotics from simple task achievement or task performance to a highly automated process for handling patients, utilizing OR personnel, accounting for and reducing error in OR supplies, and streamlining and improving overall OR efficiency and utilization.

2) The role of robots in simulation and education. Although not a primary focus of this working group, surgical simulation and surgical planning were discussed. While most of this Working Group's members felt that surgeons had neither time for nor interest in pre-surgical simulation exercises, planning for more effective use of surgical simulation as a mode of training, teaching, or readiness is needed. Suggestions for providing training were as follows.

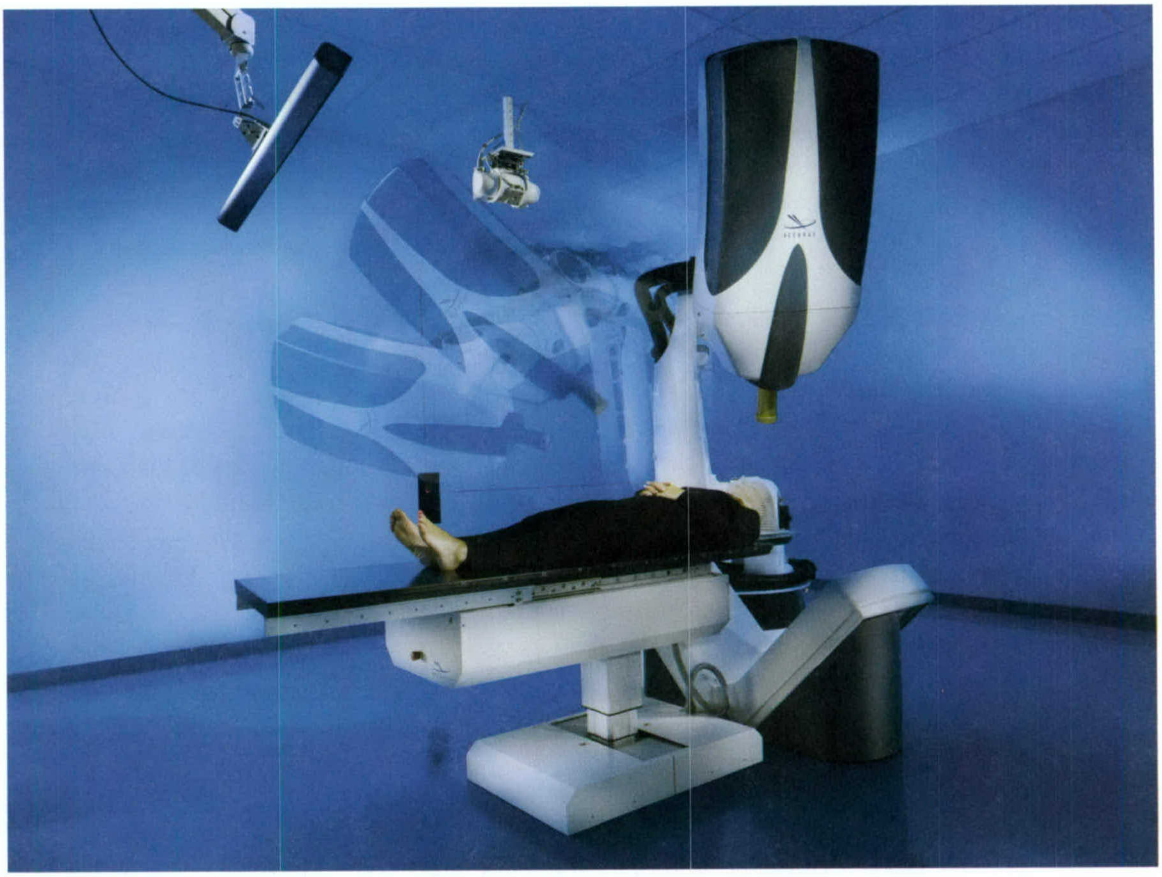

Figure 5: CyberKnife® stereotactic radiosurgery system. The system consists of a linear accelerator mounted on a six degree of freedom robot arm, along with two flat panel detectors and corresponding x-ray cameras.
(courtesy of Accuray, Inc.)

Surgical simulation incorporating robotic systems as learning or training devices could borrow concepts and technology from the airline industry. The use of airplane simulation training is highly advanced and is absolutely an industry standard. Imaging technology would need to be combined with surgical simulation software so that images such as catherization data, x-ray, CT, PET, MRI scans, and sonography data could be loaded into the robotic visualization system preoperatively, and the operative team could practice tumor removal or reconstruction techniques prior to performing the procedure. "No fly zones" for the instrumentation could be defined to limit any collateral damage. The procedure could even be recorded for playback on the actual patient. The surgical operator could be present, but the robotic system would perform the "learned" task of surgical extirpation of the tumor. The operator would simply have the ability to abort the procedure with a "stop" button during periods of hazard.

Similarly, simulation could provide remote learning exercises. By electronically linking two surgical robots, a surgical trainee could experience the movements of an experienced surgeon at a different site, seeing what the experienced surgeon is visualizing and feeling the hand movements of the experienced surgeon in a remote telementoring or teleprompting scenario. The use of surgical "tele-illustration" may also be a potentially valuable tool for training and improving surgical skills without having to practice on human beings. An entire library of "virtual simulation" cases could be developed and archived to comprise the learning materials that are needed for an entire virtual surgical training experience and perhaps even for an entire surgical residency training period.

In addition, the concept of a completely virtual hospital environment was discussed as a means for simulating all manner of surgical interactions with patients. Virtual anatomical surgical atlases and training tools for surgical instruction must be developed to initiate this effort. Subsequently, the integration of virtual surgical texts into the surgical decision making process might facilitate decision making. For example, with a host of anatomical and surgical information available, surgical operators could more easily make decisions about the modification of their own surgical techniques. This new means for practice and decision making will likely reduce operative time, increase operative efficiency and reduce costs of surgical intervention. Use of this technology would, however, require adopting principles of economy of scale as well as process improvement from industry and to treat surgical robotics more like industrial robotics.

5.3 Technical Requirements: Needed Improvements and Safety Issues

Definitions of the surgical robotic system and the robotics process (current or futuristic) are needed at the outset of discussion of technical needs for robots in the ORF. Unique capabilities of surgical robots today (compared to humans) were identified by this Working Group and include advanced

- Precision
- Accuracy
- Strength
- Dexterity
- Reproducibility
- Access to small and inaccessible parts of the human body in unfavorable environments, such as inside of an MRI or CT scanner.

Whether or not the surgical robot or the robotics system is defined as a single tool for task completion or an entire process in the ORF, a central enabling concept has not been agreed upon as of yet. An example of a robotic surgical system actually "capturing the surgeon" and providing the central direction in the OR was discussed. However, while the robotic system can be a central enabling element in the surgical process, the human control interface is and must be the focus of the total surgical process.

What can surgical robots do? Envisioning improvements and advancements in surgical robots requires, first of all, building on their unique capabilities, as indicated in the bulleted list above. Design should not be bound by the current surgical paradigm (a surgical operator with two arms and two eyes). This is a highly limiting proposition. One participant, a surgeon, stated, "You do not need just two arms…You may need ten arms to complete a task." Designing the robotic systems around the surgical functions required is a vital and pressing research need, this Working Group concluded.

Technical research needs for improving robotic surgery were identified as follows. Research must focus on: (1) Improved image control coupled with the surgical capabilities of robotics; and (2) Means for improving process planning to make a better "fit" of robots in the OR. Improved process planning requires that robots be programmed with uniform validation tools (e.g., standard benchmark tests, safety guidelines, and efficacy tests, which will vary with each surgical specialty). Development of an architecture of standard interfaces for robots is key, once the role(s) that robots or surgical robotic systems can play in the overall architecture of the ORF are defined.

Incorporating surgical robotics with surgical ontology is an important goal, both for defining the role of robots in the ORF and for achieving needed standardization of tools and processes. This development would involve using similar or comparable terms and definitions for robotics as are used for conventional surgery. In addition, definitions and standards for accuracy and precision as they relate to clinical tasks must be developed and standardized. Designing robotic procedures such as characteristic motions and task segmentation, and establishing a relationship of the robotic systems to anatomical models in the context of surgical processes and needs also must be undertaken. The end result, it is hoped, will be the development of robots not in the vacuum of what they can do, but in terms of what is needed in surgical procedures. The robotic systems could then be used in a more efficient and effective manner and have a better "fit" in the ORF environment.

Safety Issues

All of the technical needs that were identified by this Working Group could be focused towards an overarching goal: to improve the safety of surgeries and to reduce complications. Safety issues direct much of robotic systems' development today. On the one hand, safety issues place constraints on the design of these systems as they are required to conform to certain safety standards, which can limit new designs. FDA approval of any robotic system is a limiting factor because it is a driving force in bringing any new technology to market. New technology with new surgical capabilities could possibly introduce completely new risks or hazards from a safety standpoint.

On the other hand, the routine use of surgical robotics may well reduce risk and hazard, while increasing or at least enhancing patient safety in the ORF. In particular, surgical robotic systems may reduce individual variance and operator error. For some in the Working Group, achieving a degree of safety in the OR environment is a matter of understanding the risk/benefit ratios and tradeoffs of using new technologies. Such concerns lead into the area of risk assumption and product liability with regard to class action lawsuits or corporate governance issues. There is, therefore, a pressing need for engineers, technicians, and designers to work closely with surgeons to identify the potential risk and benefit ratios in using these systems.

Addressing risk and safety issues related to surgical robotic systems requires that surgeons and other OR personnel be educated about the needs for:

- holding reasonable expectations about the accuracy and precision of robotic surgical systems.
- following established guidelines for the set-up and use of surgical robotic systems.
- preparing contingency planning and undergoing training in the event of surgical robotic system failure or unanticipated events (accidents).

Recording these surgical procedures (as is done with airline flight data recorders) may be one way to improve safety and promote safe surgical practices when robotic systems are employed in the ORF. Such records of surgical data and operative interventions could be mined expressly for uncovering detail concerning practice processes and safe procedures. The issues of process improvement, total quality management, and performance improvement and modification when surgical robotics systems are employed are significant. In fact, the need for such mechanisms to be in place is absolutely vital to insuring patient safety at institutions where surgical robotics systems are routinely employed in the future.

5.4 RESEARCH PRIORITIES

There are many potential areas of research in the surgical robotics arena as the field is still developing. It was suggested that achieving error-free surgical intervention could be a "grand challenge for the field". Research areas suggested by this Working Group also included:

1) Means for improving cooperation and communication between surgical robotic systems and humans in the ORF environment to ensure safer and broader applicability of the technology.
2) Developing semi-automatic systems or shared autonomy systems incorporating both robotics technology and monitoring by surgeons.
3) Built-in safety checks for robotic systems and mechanisms for process validation to enhance safety for patients.
4) Means for mining the enormous and complicated streams of surgical data which are generated by surgeons. This data could then be used to improve the process and also in surgical simulation incorporating robotics for training purposes.

CHAPTER SIX AT A GLANCE:
INTRAOPERATIVE IMAGING

Overview

Intraoperative imaging includes the use of

- real-time imaging modalities during the surgical procedure;
- pre-operative images that are registered to the patient; and
- all associated infrastructure that is necessary to enable effective application of all such technologies.

A central issue in intraoperative imaging today is the difficulty that surgeons face in obtaining information from imaging devices in the operating room (OR). Surgeons need images presented in interactive and 3D formats. They also must be able to integrate and manipulate these images during the surgical procedure.

Clinical Needs

A range of intraoperative imaging technologies is currently available; however, their integration capabilities are limited. Consequently, these imaging technologies are not used as frequently as they might. Improvements are needed in:

- access to integrated images obtained prior to and during surgical procedures.
- training of OR staff in pre-planning and simulation tasks that are required prior to surgery and in working effectively in a multimodality environment.

Technical Requirements

Technical priorities to address these clinical needs must focus on improving the imaging systems themselves by developing:

1) readily accessible, real-time, 3D imaging capabilities in the OR.
2) flexible systems that integrate current and future imaging systems and the development of standard platforms for imaging modalities.

Research Priorities

To establish the need for intraoperative imaging, research must

1) identify specific surgical needs (per type of surgery) for intraoperative imaging.
2) evaluate intraoperative imaging outcomes and demonstrate their value.

Priorities must focus on lobbying and otherwise encouraging imaging system developers to build products that enable intraoperative integration. In addition, purchasers must play a role in this effort by demanding products that enable integration and intraoperability of imaging systems.

The full report of this Working Group appears on pages 50-55.

CHAPTER 6 :

INTRAOPERATIVE IMAGING

...THE REPORT OF WORKING GROUP 5

PARTICIPANTS

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Wolfgang Wein, Technical University of Munich
Kenneth Wong, PhD, Georgetown University Medical Center
Brad Wood, MD, NIH Clinical Center
Terry Yoo, PhD, National Library of Medicine

6.1 OVERVIEW: INTRAOPERATIVE IMAGING DEVELOPMENTS

Intraoperative imaging encompasses the use of real-time imaging modalities during the surgical procedure; the use of pre-operative images registered to the patient; and all associated infrastructure that is necessary to enable the effective use of such technologies. This Working Group addressed the use of intraoperative and preoperative imaging modalities including MRI and ultrasound, and the current status of image fusion and registration. The group also discussed visualization, image-guided surgery, tracking of instruments, and the role of new modalities such as optical imaging for diagnosis and for therapy.

The need for integrated imaging systems and improved workflow in today's operating rooms (ORs) presents both key clinical and technical issues. Poor information availability and information flow from the imaging devices to the operating room are major obstacles to improved intraoperative diagnosis and imaging. This Working Group identified the presence of PACS (picture archiving and communications) systems as almost an impediment to the needs of surgeons. Many hospitals today have "bought into" imaging, but in fact the imaging needs of surgeons cannot be met with stationary PACS whose displays are typically in 2D formats only. For surgeons, the imaging display must be in 3D, be interactive, and also be displayed so the images can be easily consulted by surgeons during a procedure. Functional platforms for a range of equipment that can integrate real-time data from imaging devices are required to meet intraoperative needs, particularly as more complex surgeries are undertaken today.

To develop and use better intraoperative devices in the OR, experts should identify particular tools, appropriate imaging modalities for different surgical procedures, and skill sets that are required for undertaking certain procedures. They should also focus on the best ways to do a procedure using imaging technologies.

6.2 CLINICAL ISSUES: THE STATE OF INTRAOPERATIVE IMAGING

The clinical need for increased use of imaging in the OR that is acquired pre- as well as intraoperatively is driven by the increasing desire to take advantage of minimally invasive procedures for the treatment of disease throughout the human body. The goal of being able to perform "therapy" at a target site while avoiding the "surgery" necessary to gain access to that site is a clear objective that can reduce patient trauma and potentially decreases the cost of treatment delivery.

State of imaging today. Intraoperative imaging technologies that are currently available include ultrasound, endoscopes/laparoscopes, nuclear probes, and gamma pens. These modalities are being used possibly more so than magnetic resonance imaging (MRI) and computed tomography (CT) at some leading U.S. institutions. In addition, optical laparoscopic imaging is widely used and biologic spectroscopy is being used particularly for certain applications such as identifying cervical neoplasia.

However, the integration capabilities of most available imaging modalities are limited. Images acquired during a procedure are typically neither integrated nor displayed with pre-operative images. Imaging modalities are not used routinely in the OR.

Development of the field. Access to integrated images that are obtained prior to and during surgical procedures is key for improving today's surgeries. However, this need is not shared by everyone in the medical community. In community hospitals, for instance, which have limited imaging systems on hand, integration is not only a non-issue, but the need for having and using new imaging technologies is not voiced by older surgeons, who feel that they already "know the anatomy." More education and training about the value of advanced imaging is therefore warranted.

Furthermore, tasks and staffing approaches must be adapted to multimodality imaging environments. For instance, pre-planning and simulation prior to surgery are necessary as 3D modeling should be done prior to going into the OR. Therefore, surgical staffs must be trained and well-versed in performing these pre-surgery functions. In addition, more technical personnel need to be included on the surgical team for operating the imaging equipment. Other trained and educated OR staff, such as nurses and OR coordinators, have to "buy in" to using the equipment and scheduling its use. According to one Working Group member: "If [imaging modalities] are difficult to use, people don't use them – the energy barrier is too great to simply have the image show up."

Operating rooms themselves need to be reconfigured for more effective use to be made of advanced imaging. This Working Group noted that the traditional OR was not designed for today's complex workflow and for using complicated technology such as MRI or CT. New designs are needed to obtain adequate intraoperative visualization of integrated images. There is also a pressing need to develop appropriate display systems (LCD panels, virtual screens, and so on) that suit clinical needs in terms of size and placement in the OR.

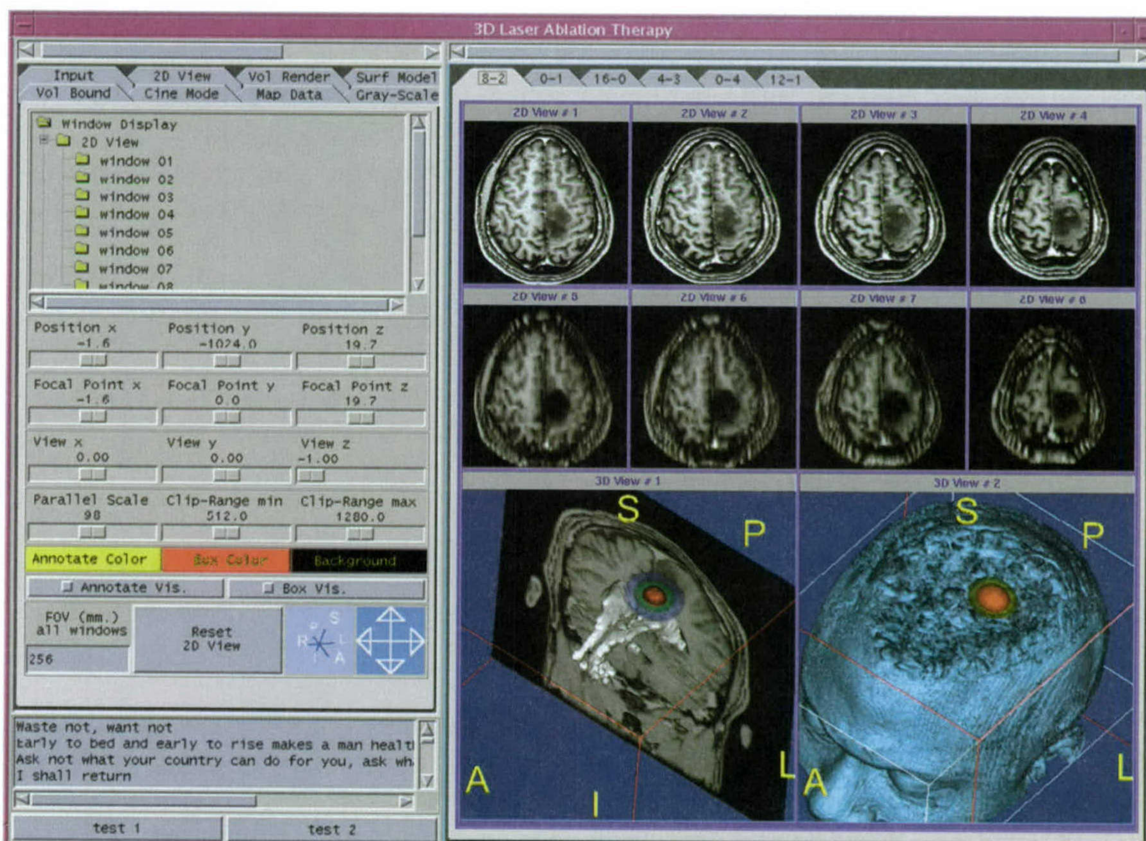

Figure 6: 3D laser ablation therapy
(courtesy of Ferenc Jolesz, MD, Brigham and Women's Hospital)

6.3 Technical Requirements: Needed Improvements in Imaging Quality and Efficacy

Making intraoperative imaging a clinically useful and welcomed option requires technical teams of developers to address the following needs.

1. Improved image quality and image guidance. Intraoperative imaging quality in its current state is deemed to be poor, overall. Its adequacy is also in question. Particularly, this Working Group noted that PACS systems (which are, in the main, tools for radiologist to view medical images – *not* tools for surgeons) available in the OR rarely have a 3D imaging capability available. Typical PACS in the OR tend to simply duplicate the "wall-of-film" approach used outside of the OR: that is, they mimic the way plain films are displayed in the radiology reading room. As such, they cannot meet the needs of surgeons for intraoperative, real-time imaging and display.

Not only improved quality but also improved image guidance systems are needed to meet surgical requirements. PACS systems without 3D capabilities do not allow for routine surgical planning. To illustrate this point, an example was provided indicating the different imaging needs of radiologists and neurosurgeons working with an aneurysm. Radiologists need to specifically visualize the aneurysm, while surgeons must be able to visualize the real-time surgical process. Therefore, surgeons need 3D capabilities so that they can assess the aneurysm and blood vessels from multiple dimensions and determine the surgical directions that they must take.

2. Improved reliability of image tracking. More reliable tracking of images that are taken during surgical procedures may be particularly helpful to meet the need for improved guidance during surgeries. A related need is for an automated data keeping system or book marking technique to identify and archive images taken in MR, CT, and a variety of other imaging formats during different phases of surgery.

3. Improved registration techniques. Registration needs must also be addressed by technical teams who should be tasked with developing a standardized or common methodology. Vendor-specific algorithms that are used today for some modalities are inadequate for many purposes. Standardization of a universal imaging and registration methodology is a key element on which to build navigational systems (robotic or otherwise) that are able to use registered data. Ideally, in addition, an advanced image-based system may be developed that is smart enough to manipulate images and co-register them, as needed.

4. Improved segmentation process. Segmentation is seen as an important part of intra-operative image utilization. First and foremost, it needs to be applied to the 3D source images in order to extract any sort of surface information from them, for the purpose of registering images via surface matching, or providing realistic organ visualization during the procedure. However, segmentation is not a feature typically provided by most commercial visualization packages. Segmentation also falls into the category of "tampering with the data," in the sense that any rule applied to an image to define a

surface will inevitably compromise the data to some extent. It is clear that universal segmentation algorithms are unlikely to ever become entirely automatic. Hence there is a need for intuitive interfaces to permit human intervention in the selection of the desired region, as well as to provide an evaluation of the consistency of the results.

Key technical requirements in intraoperative diagnosis and imaging are:

- flexible imaging and registration systems to integrate both current and developing imaging systems, preferably using only one standard imaging platform for all of the imaging modalities.

- adaptable, modular systems for increased use of multimodality imaging in the OR.

- optimum means for visualizing fused images and images registered to the patient's anatomy, such as those used in image-guided systems.

6.4 RESEARCH PRIORITIES

Research Needs. This working group identified six research tasks that are essential for advancing the field of intraoperative imaging:

1) Developing targeted imaging integration systems. Integrated displays that allow multiple imaging modalities to be visualized simultaneously must be designed. There is also a need for integrated tracking and registration across modalities, and across tools and other equipment so that all data are inherently registered to a single, common coordinate system.

2) Developing advanced registration techniques. Technique must be developed to integrate preoperative imaging with 3D real-time intraoperative imaging. There is also a need to research effective error measurement, particularly for use with non-rigid image registration.

3) Developing as-needed clinically directed imaging systems. Instead of bringing current/traditional radiology systems into the OR, new imaging systems should be designed from the ground up, based on the requirements of the OR. Similarly, there is a need for better clinically related training of biomedical engineers, so that they can move from the "bench to the bedside" and be better able to address these clinical design issues.

4) Developing a standardized nomenclature. There is a pressing need to develop a standardized, common language for describing how images have been formatted.

5) Identifying specific surgical needs for intraoperative imaging. More research should be focused on identifying types of imaging that are needed today and in

the Operating Room of the Future (ORF). *Note*: This conclusion is based on knowledge of today's technologies, not on advances like molecular imaging which, as this Working Group recognizes, could very well change the kinds of surgeries and treatments that are practiced in the ORF. However, there is a need to study today's imaging modalities, including functional MR and position emission tomography (PET), as the building blocks on which future developments will be based. For example, researchers need to examine potential uses of optical and molecular imaging data that can be co-registered with high-resolution anatomical imaging to improve surgical approaches to tumors.

6) Evaluating outcomes resulting from use of intraoperative imaging. The value of intraoperative imaging still needs to be better established. Standards must also be developed by which to compare images that are integrated. These standards would allow the medical community to conclude, for example, that fusion of MR and PET is better than fusion of CT and PET.

<u>Research Priorities</u>. Planning for these research developments must take a two-fold approach. Activities must focus on:

1. Lobbying industry and individual manufacturers to build imaging products that enable intraoperative integration. Developers, until now, have created for the most part stand-alone proprietary imaging systems. DICOM has been offered as a step toward standardizing imaging formats across manufacturers. Each imaging equipment manufacturer, however, still maintains proprietary fields relating to certain aspects of the images. As a result of this practice, generic software cannot deal seamlessly with multiple imaging modalities that are generated from different manufacturers' equipment.

2. Persuading large purchasers of imaging equipment, such as the military, to require that imaging systems meet certain standards and compatibility requirements. A market-driven approach may result in workable intraoperative imaging systems for the ORF.

CHAPTER SEVEN AT A GLANCE:
SURGICAL INFORMATICS

Overview

Surgical informatics is in a nascent phase as a discipline today. By definition, surgical informatics is the collection, storage/organization, retrieval, sharing, and rendering of biomedical information that is relevant to the care of the surgical patient. Its purpose is to seamlessly use computer-based informatics programs to provide comprehensive and decision making support to the health care team. As a result of applying surgical informatics to both usual and problematic surgical cases, improved decision making and problem solving in surgery are possible.

Clinical Needs

Significant clinical issues that are currently limiting the development of surgical informatics include disparate information systems, and few checks and balances in available informatics systems to guide surgeons in their tasks and decisions. Clearer requirements for information and its presentation to surgeons and other professionals have to be developed and made available during surgeries via text, voice, and video images. Particular attention must be devoted to building informatics systems that integrate preoperative, operative, and postoperative information and making it available where and when needed. Errors in the operating room (OR) related to incomplete information can then be avoided.

Technical Requirements

Standards for procedures and use of surgical informatics must be defined and implemented. These standards should encompass uniform language/terminology as well as uniform and seamless electronic medical records that will include patient and surgical information, billing, and patient safety issues. Surgical informatics technology for the Operating Room of the Future (ORF) needs to encompass processing, storing, and indexing details on biomedical/kinetic markers, tissue/pathologic recognition, and other information for instant retrieval by surgeons.

Research Priorities

Three key research priorities that were identified by this Working Group are:
1) Standards development in surgical informatics; 2) Precisely defined uses of surgical informatics systems (e.g., for optimizing the skills of surgeons, and for teaching students differently and helping them to perform better); and 3) Intelligent agents that can become virtual experts/consultants which will work with surgeons in the OR.

The full report of this Working Group appears on pages 57-62.

CHAPTER 7 : SURGICAL INFORMATICS

...THE REPORT OF WORKING GROUP 6

PARTICIPANTS

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Howard Dady, Walter Reed Army Medical Center
Anthony Gallagher, PhD , Emory University
Gerry Moses, PhD, Telemedicine and Advanced Technology Research Center (TATRC)
Stephen Schimpff, MD, University of Maryland Medical Center (retired)
Jianchao Zeng, PhD, Howard University
James Zhang, PhD, Georgetown University

7.1 OVERVIEW: IDENTIFYING THE WORK OF A NEW FIELD

Surgical informatics is in a nascent phase as a discipline today. By definition, surgical informatics is the collection, storage/organization, retrieval, sharing, and rendering of biomedical information that is relevant to the care of the surgical patient. Its purpose is to seamlessly use computer-based informatics programs to provide comprehensive and decision making support to the entire health care team.

Medical informatics overall has made great progress in recent years but surgical informatics specifically has lagged in development, usage and, hence, in usefulness. Since the operating room is inherently high cost and high risk along with being a key driver of hospital revenue, it follows that effective surgical informatics systems should be developed. Surgeons, anesthesiologists, nurses, supply managers, and hospital management could all benefit from surgical informatics, with the result that operative procedures would become safer, of higher quality, and more efficient.

It is interesting to observe that the operating room and perioperative environment employ increasingly sophisticated technology such as laparoscopes, monitors and video devices, along with access to digitized laboratory and imaging data. Still, software to aid in direct care has been less than impressive, especially given the progress in recent years with the electronic medical record in use elsewhere in the hospital setting. This deficiency in effective information for the OR suite has frustrated health care professionals and slowed perioperative environment innovation. It is not in anyone's best interest to have a situation where some elements and systems are automated while others remain paper based.

As this Working Group noted, the basic needs in surgical informatics involve, first of all, getting patients from the clinic to a pre-operative holding area and then to the operating room (OR) with the correct laboratory, imaging, and other needed data, including the specific tools needed for the surgery. A related issue involves enabling everyone to make optimal use of this surgery-related information, data, and surgical tools. Improved decision making and problem solving in the perioperative environment should result from applying surgical informatics to both usual and problematic surgical cases and needs.

7.2 Clinical Issues: Achieving Optimal Performance by Using Surgical Informatics in the Operating Room

The significant issues that are currently limiting the development of surgical informatics are typical of most new disciplines. These issues include the presence of few, accepted standards to guide the field's development, and limited examples in surgical informatics that have demonstrated success. Other limitations include the following issues:

- Disparate information systems that hamper development. According to one Working Group member, surgical informatics is a very "fractured field," with pieces and parts that do not yet work together.

- Competing agendas among stakeholders. This problem may explain why proprietary systems rather than integrated equipment are more available today.

- No checks and balances in current informatics systems. Instead, surgical success is dependent upon, as this Working Group noted, the "frailties of human memory and judgment," which limit quality control.

- Aversion among surgeons to using new information technologies. Resistance to change has also characterized the slow move from paper to paperless systems.

Clearly, these clinical limitations must be addressed. Integration of these disparate "pieces and parts" of today's surgical informatics technologies has to become a top priority among all stakeholders.

In particular, a clearer requirement must be defined for the surgery-related information that is needed by the health care team. At least three categories of information and assistance need to be available to surgeons:

1. Text-based and voice data and video images (allowing captured data to be fed into the informatics system).

2. Intelligence or content-based retrieval mechanisms (allowing the surgeon to retrieve information that is similar to his current operative findings and so compare features or other details).

3. Means for retrieving and rendering information – by voice and other sensory output, or by display for visualization such as in a 3D model – that the surgeon can use during an operation.

Other issues limiting the development of the field that must be addressed are the following:

- Getting the Right Information. The unique environment of the OR – busy, noisy, potentially chaotic – must influence how the surgical information is presented. Visual presentation is appropriate for some information while auditory feedback may not work as well, for instance. Human factors that are unique to the OR and its special environment should be studied. For example, designers of instrumentation have tried to build 3D camera systems for surgery when, in fact, improving imaging quality in the OR might be more important.

- Starting with the Basics. To build effective systems, experts must examine today's disparate systems and the high amount of error in today's OR. The new system itself needs to be interactive and wireless, and it should integrate preoperative, operative, and postoperative information. It should do so precisely and the information should be made available where and when needed. Complete and accurate patient records are needed to ensure that the correct surgical tools are available for surgeries. Today, many errors in the OR can be traced to incomplete patient information and preparation.

  Currently, there are no automatic, smart, or otherwise nonhuman checks and balances that will note if medication has not been given or if a surgical tool set is incomplete prior to the start of a surgery. Even more problematic is the absence of means for assuring that patients have been properly prepared for surgeries when they enter the OR. Information technology must ensure that encounters with the patient have been tracked and information about them is available and retrievable during surgeries.

- Fixing Today's Informatics Systems. Ideally, surgical informatics should be mechanical and repetitive. The systems should organize a range of detail so that the surgeon and anesthesiologist do not have to personally examine more mundane details that are gathered about patients and their surgeries (are they allergic to a medication, did they get properly prepared for surgery, and so forth). Rather, the system should automatically review this data and alert personnel to any potential problems.

  Solutions to the limitations of current systems are not solely technical in nature, or at least they do not require brand new and advanced development, this Working Group noted. Rather, what is key is an organizational effort to "buy into" the existing technology and devise a system in which all pieces speak the same language. The problem of competing agendas among surgeons, anesthesiologists, nurses, hospital administrators, and the information technology and equipment industries must be faced and managed.

At the same time, a nationally acceptable set of standards and data to be collected must be developed. The content of this database should begin with the needs of health care professionals in the OR and then migrate across the whole hospital. Currently, surgeons are devising workarounds for their information systems or working with homegrown systems that are unreliable over the long term. More productive solutions for data standards and collection are obviously needed.

7.3 Technical Needs: Foremost, Standards for Surgical Informatics

As in all developing fields, a set of unified standards for procedures needs to be developed. Surgical informatics standards ought to be mandated, in fact, for advanced and safe surgeries in the future, this Working Group agreed. The Working Group also identified the players who should participate in the development of surgical informatics standards, including government decision makers, the hospital industry, the IT and equipment industries, and surgeons. A periodic review of these standards ought to take place every 5-10 years.

The value of defining and using technical standards for surgical informatics paves the way for insisting that all related equipment be integrated and work well together. The federal government may very well be the driver for requiring these standards.

Today, there are no examples of an integrated hospital where all the equipment works together. This is not because the equipment does not work but because it cannot, without standards, work together. Planning for equipment development must begin anew and from hereon in, purchasers must insist that the new devices and systems follow specific standards (as these standards become articulated and agreed upon).

These standards ought to be aimed toward encompassing uniform

- language/terminology, possibly developed with assistance from the National Library of Medicine and its well established classification and indexing systems.

- electronic medical records including patient and surgical information, billing and inventory details, and patient safety issues. These records, in addition, ought to be seamless and transcend institutional and other boundaries.

These standards should ensure that information is readily accessible to surgeons, whether the data are centrally stored and/or encoded and designed to be worn by the patient.

Tomorrow's surgical informatics systems. Surgical informatics systems must encompass the entire patient experience including pre-op, surgery, and post-op. Technology for these systems must be in a language and framework that is global and flexible. It also must have a capacity to evolve and be upgraded.

Imaging that is included as part of the surgical informatics systems can have multiple uses. Apart from its use during surgery, the imaging can be used for educational purposes. For example, procedures that are recorded can be used for simulation and teaching. As a result of using simulations, surgical training can be systemized. Simulation can also be useful for surgical planning as shown in the figure below.

This Working Group believes that technology for the ORF already exists for today's usual surgical procedures. What is needed is determining ways to accrue the data beyond mere video rendering. The Working Group stressed the need for storing and integrating multimodal/sensory inputted data, focusing on data streams of video that will, for example, enable anatomic pattern recognition. Video data streams may also include details on biomedical/kinetic markers; tissue/pathologic recognition; patient monitoring; and perhaps audio and tactile data. This information should be processed, stored, and indexed for instant retrieval by surgeons on an as-needed basis. A caveat about information storage was provided by a group member, who noted that the goal should be to store more information better than the human brain does.

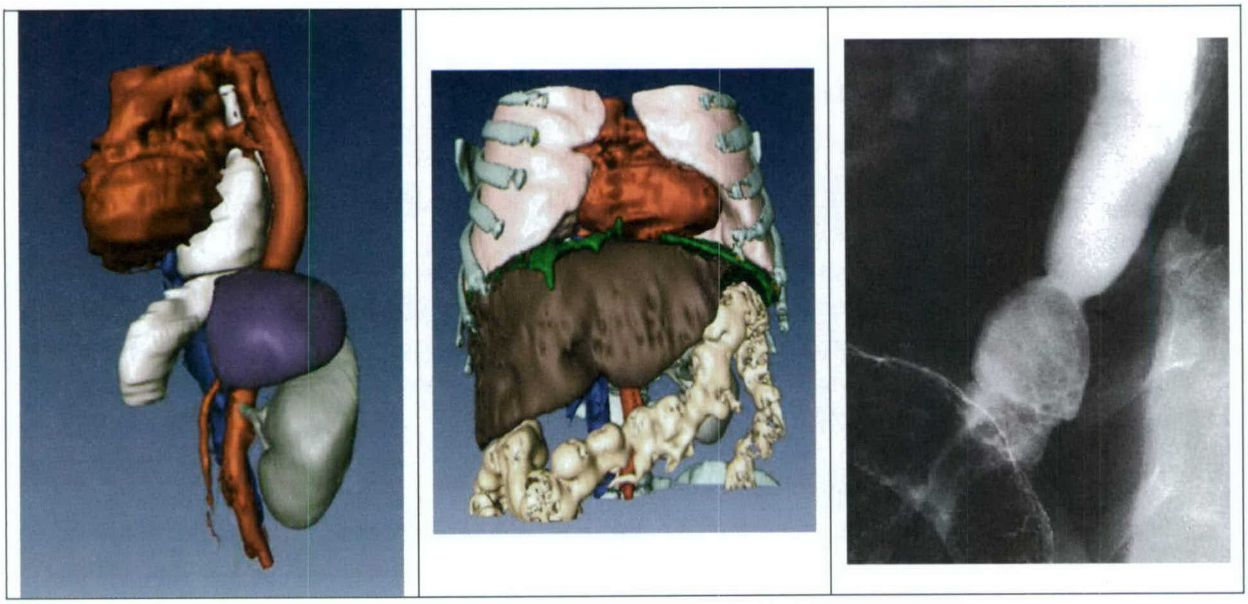

Figure 7: 3D visualization for surgical planning. The left and middle images show 3D reconstructions of a patient with a large hiatal hernia (stomach bulging up into chest) for whom a laparoscopic repair is planned. These images are visualized on the computer to allow the surgeon to study and "fly" through the anatomy preoperatively, paying particular attention to relationships between the esophagus and herniated fundus to the heart, lung, aorta, etc. The surgeon can also rehearse port placement, the planned sequence of dissection, and other operative procedures. These reconstructions can greatly enhance patient care over the traditional approach of studying the plain film available from a barium swallow (shown in the right image here).

(courtesy of Adrian Park, MD, Barry Daly, MD, and Ivan George, Univ. of Maryland Medical Center)

Protocols for accruing these data by using intelligent agents or smart means of manipulating and rendering it ought to be established and this is a key technical challenge. These intelligent agents should enable:

- Automated content extraction and information synthesis (based on video, CT, other modalities, and case outcomes, and on pattern recognition)
- Anticipation of next steps
- Decision support
- Natural language content retrieval

This information may be presented visually during surgeries in different formats. These formats might include images that have been registered and overlaid. The presentation might also be auditory, tactile, or even be achieved by providing olfactory cues to surgeons.

Ultimately, these intelligent agent systems could function as virtual experts (incorporating the knowledge of numerous real-life surgical experts) to assist surgeons, anesthesiologists, and nurses. These virtual experts could provide information and opinions in real time during surgeries about the best practices to be used, and could advise the surgeon. They could also be used for educational purposes to help students learn a particular procedure.

7.4 Research Priorities

Research needs and priorities suggested by this Working Group are aimed at improving the development and use of surgical informatics. These include:

Standards Development. There is a need for arranging a multi-level conference among representatives from government, equipment and information technology vendors, the hospital industry, and the surgical community, to set surgical informatics standards, like the DICOM standard that was developed for the imaging arena. The federal government should take the lead in this effort.

Defining Uses of Surgical Informatics. Surgical informatics systems and their standards ought to develop from the perspective of a surgeon and aim to optimize his or her skills. This development can also help to teach students in a different way; that is, using surgical informatics may allow them to practice procedures in more specific detail and so perform better.

Development of Intelligent Agents. There is a need to investigate and develop a variety of intelligent agents which can be virtual experts or consultants of two types: non-opinionated and opinionated. A non-opinionated agent provides guidance based on "hard" data, such as anatomy and physiology. For example, a non-opinionated agent may warn the surgeon that he is too close to critical vessels or nerves. An opinionated agent may contain a database of different approaches for a particular course of action and be guided by thousands of similar cases to assist the surgeon.

Chapter 8: Appendices

8.1 Appendix A. Workshop Program

8.2 Appendix B. Workshop Participants

8.3 Appendix C. Suggested Bibliography

Appendix A. Workshop Program

Day 0 (Thursday), March 18, 2004

Afternoon: participants check-in
1800-2000 Opening ceremony: reception and buffet
2000-2100 Organizing committee and Working Group leaders meeting

Day 1 (Friday), March 19, 2004

0730-0830 Breakfast buffet
0800-0815 Welcome, Workshop format and objectives, Kevin Cleary, PhD, Georgetown

0815-1000 Plenary Session I: Clinical scenarios (chair: Michael Pentecost, MD, Georgetown)
0815-0835 Perspective: Evolution of surgery & future promises. William DeVries, MD, Walter Reed Army Medical Center
0835-0855 CIMIT program on the Operating Room of the Future. David Rattner, MD, Massachusetts General Hospital (MGH)
0900-1000 Panel discussion of surgical specialties. (moderator: Seong K. Mun, PhD, Georgetown). Panel:
Neurosurgery: Joseph Hahn, MD, Cleveland Clinic
General surgery: Michael Marohn, MD, USUHS
Cardio-thoracic surgery: Philip Corcoran, MD, Walter Reed Army Medical Center
Urology: Noah Schenkman, MD, Walter Reed Army Medical Center
General surgery: Ho Young Chung, MD, PhD, Georgetown University
Orthopaedics: Cato Laurencin, MD, PhD, University of Virginia
Anesthesiology: Warren Sandberg, MD, MGH

1000-1030 Morning coffee break

1030-1200 Plenary Session II: Technology Components (chair: Gerry Moses, PhD, TATRC)
1030-1050 Device independence for the OR. Richard Bucholz, MD, St. Louis University
1050-1110 Robotics state-of-the-art and future scenarios. Russell Taylor, PhD, Johns Hopkins
1110-1130 Image-guided therapy. Ferenc Jolesz, MD, Brigham and Women's Hospital
1130-1150 Workflow. Heinz Lemke, PhD, Technical University of Berlin
1150-1200 Discussion

1200 Group photo on hotel front steps

1200-1330 Buffet lunch

1330-1500 Plenary Session III: Other Topics (chair: Terry Peters, PhD, Robarts Research Institute)
1300-1345 Pittsburgh OR of the Future. Amin Kassam, MD, University of Pittsburgh
1345-1400 Interventional oncology. Brad Wood, MD, NIH
1400-1415 Future of imaging. Harvey Eisenberg, MD, Healthview.
1415-1430 DaVinci future developments. Chris Hasser, PhD, Intuitive Surgical
1430-1445 Interventional suite of the future. Vance Watson, MD, Georgetown
1445-1500 Breakout group instructions. Kevin Cleary, PhD

1500-1530 Break

1530-1700 Breakout Session 1: Current status and clinical requirements
Task 1: Define the current status of the operating room relevant to your Working Group (review questionnaire results and pre-workshop report, get comments from Working Group members)
Task 2: Establish the requirements for the next generation operating room. Prepare summary statement for presentation at plenary session to follow.

1700-1800 Plenary Session IV Breakout groups' reports (5 minutes per group; 5 minutes Q & A (Chair: Gilbert Devey, NSF)

1900-2100 Evening dinner with keynote speaker
Speaker: Mehran Anvari, MD, Hamilton, Ontario, Canada
Discussant: Lou Kavoussi, MD, Johns Hopkins

Day 2 (Saturday), March 20, 2004

0700-0800 Breakfast buffet

0800-0930 Plenary Session V: Special Topics
0800-0845: International Session (Chair: Heinz Lemke, PhD, Technical University of Berlin)
0800-0815: OR2010 project. Randy Ellis, PhD, Queens University, Canada
0815-0830: Laparoscopy and haptics. Alois Knoll, PhD, Technical University of Munich
0830-0845: Perspectives from Japan. Hiroshi Iseki, MD, PhD, Tokyo Women's Medical University
0845-0930: Education and Therapy Team of the Future (Moderator: Anthony Gallagher, PhD, Emory University)
Warren Grundfest, MD, UCLA
Bruce Jarrell, MD, University of Maryland

1000-1130 Breakout Session 2: Research priorities formulation by team members
Task 1: Based on the requirements identified in the previous Breakout Session, identify and prioritize research areas.
Task 2: Configure the team for the Operating Room of the Future including the types of personnel needed and the training requirements.

1130-1200 Break (hotel room check out)

1200-1330 Working lunch in conference room (moderator: Kevin Cleary, PhD)
Breakout groups report (5 minutes per group, 5 minutes Q & A)
Workshop summary
Instructions to group leaders for preparing report
Close of workshop

Appendix B. Workshop Participants

NAME	DEGREE	AFFILIATION
Anderson, James	PhD	Private consultant
Anvari, Mehran	MD, PhD	McMaster University
Armand, Mehran	PhD	Johns Hopkins University
Brazaitis, Michael	MD	Walter Reed Army Medical Center
Brown, Michael	MBA	General Electric Global Research
Bucholz, Richard	MD	St. Louis University
Burgess, James	MD	Inova Fairfax Hospital
Calcagni, Dean	MD	TATRC, Army Medical Command
Carignan, Craig	PhD	Georgetown University
Cartzendafner, Chris		Karl Storz Endoscopy
Chouikha, Mohamed	PhD	Howard University
Chung, Ho Young	MD, PhD	Georgetown University
Clarke, Laurence	PhD	National Cancer Institute
Cleary, Kevin	PhD	Georgetown University
Clinthorne, Neal	PhD	Xoran Technologies, Inc.
Clyburn, Conrad	MS	TATRC, Army Medical Command
Collmann, Jeff	PhD	Georgetown University
Cojocaru, Dorian	PhD	University of Craiova
Corcoran, Phil	MD	Walter Reed Army Medical Center
Dady, Howard		Walter Reed Army Medical Center
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Appendix C. Bibliography

This bibliography was generated from the pre-Workshop questionnaire responses from the workshop's participants and is reproduced here for the convenience of the reader.

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Additional Resources

The September 2003 issue of *Seminars in Laparoscopic Surgery* is on "The Operating Room of the Future (Part II)."

The December 2003 issue of *Surgical Clinics of North America* is on "Robotics in Surgery."

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